Federal Register

Friday
June 26, 1998

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Part 400, et al.
Medicare Program; Establishment of the Medicare+Choice Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 400, 403, 410, 411, 417, and 422

[HCFA–1030–IFC]

RIN 0938–AI29

Medicare Program; Establishment of the Medicare+Choice Program

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: The Balanced Budget Act of 1997 (BBA) establishes a new Medicare+Choice (M+C) program that significantly expands the health care options available to Medicare beneficiaries. Under this program, eligible individuals may elect to receive Medicare benefits through enrollment in one of an array of private health plan choices beyond the original Medicare program or the plans now available through managed care organizations under section 1876 of the Social Security Act. Among the alternatives that will be available to Medicare beneficiaries are M+C coordinated care plans (including plans offered by health maintenance organizations, preferred provider organizations, and provider-sponsored organizations), M+C ''MSA'' plans, that is, a combination of a high deductible M+C health insurance plan and a contribution to an M+C medical savings account (MSA), and M+C private fee-for-service plans.

The introduction of the M+C program will have a profound effect on Medicare beneficiaries and on the health plans and providers that furnish care. The new provisions of the Medicare statute, set forth as Part C of title XVIII of the Social Security Act, address a wide range of areas, including eligibility and enrollment, benefits and beneficiary protections, quality assurance, participating providers, payments to M+C organizations, premiums, appeals and grievances, and contracting rules. This interim final rule explains and implements these provisions.

In addition, we are soliciting letters of intent from organizations that intend to offer M+C MSA plans to Medicare beneficiaries and/or to serve as M+C MSA trustees.

DATES: *Effective date:* This interim final rule is effective July 27, 1998.

Comment period: Comments will be considered if received at the appropriate address, as provided below, no later than September 24, 1998.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1030–IFC, P.O. Box 26688, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1027–IFC Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT:

Provider Sponsored Organizations, Aaron Brown, 410–786–1033.

M+C Private Fee-For Service Plans, Anita Heygster, 410–786–4486.

M+C MSA Plans, Cindy Mason, 410–786–6680.

Applications, Robert King, 410–786–7623.

Quality Assurance, Brian Agnew, 410–786–5964.

Payment/ACRs, Al D'Alberto, 410–786–1100.

Encounter Data, Cynthia Tudor, 410–786–6499.

Federal/State, Rebecca Cardozo, 410–786–0300.

Beneficiary Appeals, Valerie Hart, 410–786–6690.

Enrollment, Debe McKeldin, 410–786–9159.

Information Campaign, Jan Drass, 410–786–1354.

Contracts, Chris Eisenberg, 410–786–5509.

General Issues, Tony Hausner, 410–786–8290.

General Issues, Dorothea Musgrave, 410–786–8290.

SUPPLEMENTARY INFORMATION:

I. Background

A. Balanced Budget Act of 1997

Health care benefits covered under the Medicare program are divided into two parts: hospital insurance, also known as ''Part A,'' and supplementary medical insurance, also known as ''Part B.'' Health care services covered under Part A include: inpatient hospital care, skilled nursing facility care, home health agency care, and hospice care. Part B coverage is optional and requires payment of a monthly premium. Part B covers physician services (in both hospital and nonhospital settings) and services furnished by certain nonphysician practitioners. It also covers certain other services, including: clinical laboratory tests, durable medical equipment, medical supplies, diagnostic tests, ambulance services, prescription drugs that cannot be self-administered, certain self-administered anti-cancer drugs, some other therapy services, certain other health services, and blood not covered under Part A.

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Public Law 105–33), enacted August 5, 1997, added sections 1851 through 1859 to the Social Security Act (the Act) to establish a new Part C of the Medicare program, known as the ''Medicare+Choice Program.'' Note that hereinafter, unless otherwise indicated references to the statute are references to the Act. (The existing Part C of the statute, which included provisions in section 1876 governing existing Medicare health maintenance organization (HMO) contracts, has been redesignated as Part D.) Under section 1851(a)(1), every individual entitled to Medicare Part A and enrolled under Part B, except for individuals with end-stage renal disease, may elect to receive benefits through either the existing Medicare fee-for-service program or a Part C M+C plan.

The introduction of the M+C program represents what is arguably the most significant change in the Medicare program since its inception in 1965. As its name implies, the primary goal of the M+C program is to provide Medicare beneficiaries with a wider range of health plan choices to complement the Original Medicare option. Alternatives available to beneficiaries under the M+C program include both the traditional managed care plans (such as HMOs) that have participated in Medicare on a capitated payment basis under section 1876 , as well as a broader range of plans comparable to those now available through private insurance. Specifically, effective January 1, 1999, section 1851(a)(2) provides for three types of M+C plans:

- M+C coordinated care plans, including HMO plans (with or without point of service options), provider-sponsored organization (PSO) plans, and preferred provider organization (PPO) plans.

- M+C medical savings account (MSA) plans (that is, combinations of a high deductible M+C health insurance plan and a contribution to an M+C MSA).
- M+C private fee-for-service plans.

In addition to expanding the types of available health plans, the M+C program introduces several other fundamental changes to the private health plan sector of the Medicare program. These changes include:

- Establishment of an expanded array of quality assurance standards and other consumer protection requirements.
- Introduction of an annual coordinated election period. This election period, to be conducted in November for a January effective date, will feature a phased in lock-in of enrollees to the plan they have elected during this coordinated election period. In addition, the annual coordinated election period will include the distribution by HCFA of uniform, comprehensive information about participating plans that is needed to promote informed choices by beneficiaries.
- Revisions in the way we calculate payment rates to the plans that will narrow the amount of payment variation across the country and increase incentives for plans to operate in diverse geographic areas.
- Establishment of requirements concerning participation procedures for physicians and other health care professionals in M+C plans, including prohibitions on interference with advice to enrollees.

These requirements will bring about changes for beneficiaries, for physicians and other health care providers, for managed care organizations that now contract with Medicare as well as those that will be able to contract with Medicare for the first time, and for HCFA and the States. The specific areas addressed by the different sections of the statute are as follows:

- Section 1851—Eligibility, election and enrollment
- Section 1852—Benefits and beneficiary protections
- Section 1853—Payments to M+C organizations
- Section 1854—Premiums
- Section 1855—Organizational and financial requirements for M+C organizations
- Section 1856—Establishment of standards
- Section 1857—Contracts with M+C organizations
- Section 1859—Definitions and miscellaneous provisions

As provided for in section 1856(b)(1), this interim final rule (1) incorporates the new M+C provisions into the Medicare regulations, (2) interprets the new statutory provisions in Part C, and (3) establishes by regulation new standards under the M+C program. Other provisions of the BBA addressed in this interim final rule include:

- Section 4002—Transitional rules for current HMO Medicare program.
- Section 4003—Conforming changes in the Medigap program.
- Section 4006—M+C MSAs.

We note that in February, 1998, the President issued an Executive Order directing the Secretary to comply to the extent possible through administrative activities with the standards contained in the Consumer Bill of Rights and Responsibilities. Therefore, as discussed in several sections of this preamble, we have taken these standards into consideration in developing the regulations contained in this interim final rule. We have also incorporated conforming provisions consistent with other parts of the Medicare statute, such as exempting services under M+C coordinated care plans from the anti-referral provisions in section 1877.

In several places in this preamble, we indicate that HCFA intends to develop additional policy guidance or instructions. In doing so, we will use a formal rulemaking process and allow for review by the Office of Management and Budget pursuant to the requirements of the Paperwork Reduction Act of 1995, wherever it is appropriate to do so.

B. Codification of Regulations

The regulations text set forth in this interim final rule is codified in 42 CFR Part 422—Medicare+Choice Program. (Note that new part 422 was established in our April 14, 1998 interim final rule on PSOs (63 FR 18124).) The current Medicare regulations for managed care organizations that contract with HCFA under section 1876, or for health care prepayment plans (HCPPs) that are paid under section 1833(a)(1)(A), will continue to be located in 42 CFR part 417, Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans. Although the part 422 provisions will eventually supersede the regulations in part 417 for contracts with risk-bearing HMOs and competitive medical plans (CMPs), there are some purposes for which the part 417 provisions will continue in effect for a transitional period. Also, various provisions of section 4002 of the BBA provide for the continuation of cost-based contracts under section 1876 and of agreements with HCPPs under section 1833(a). Thus, the part 422 regulations cannot entirely replace the part 417 regulations at this time. (Both transitional provisions and those relating to cost-based contracts and HMOs are discussed in detail below in the appropriate sections of this interim final rule.)

For the convenience of organizations that contract with HCFA only under the M+C program, we are including in part 422 both new requirements that implement newly enacted provisions in Part C and existing requirements from part 417 that also will be imposed under Part C. For transitional requirements, which could logically appear in both parts, we are setting forth the full requirements in part 422 and referencing them in part 417. Requirements that apply to organizations that contract with HCFA, or are paid by HCFA, only under section 1876 or 1833(a) will remain in part 417. Regulations implementing the provisions of section 1310 of the Public Health Service Act concerning Federally-qualified HMOs also remain in part 417.

C. Organizational Overview of Part 422

The major subjects covered in each subpart of part 422 are as follows:

- Subpart A—Definitions, including definition of types of plans, application process, and user fees.
- Subpart B—Requirements concerning beneficiary eligibility, election, enrollment and disenrollment procedures, and plan information and marketing materials.
- Subpart C—Requirements concerning benefits, point of service options, disclosure of information, access to services, confidentiality of enrollee records, advance directives, and beneficiary protection against liability.
- Subpart D—Quality assurance standards, external review, and deeming of accredited organizations.
- Subpart E—Organizational relationships with participating entities including the prohibition against interference with health care professionals' advice to enrollees, physician incentive requirements, and special rules for M+C private fee-for-service plans and private contracts with health care professionals.
- Subpart F—Payment methodology for M+C organizations, coverage that begins or ends during inpatient hospital stays, hospice care, and encounter data requirements.
- Subpart G—Requirements concerning terms and conditions for receiving capitated payments, limits on premiums and cost sharing, determination of adjusted community rate, and prohibition of State-imposed premium taxes.

- Subpart H—Requirements concerning provider-sponsored organizations (PSOs).
- Subpart I—Organization compliance with State law and preemption by Federal law.
- Subpart K—General contract and enrollment requirements, administration and management, and procedures for nonrenewal or termination of contracts.
- Subpart L—Effect of change of ownership or leasing of facilities during term of contract.
- Subpart M—Requirements concerning beneficiary grievances and organization determinations and appeals.
- Subpart N—Requirements and procedures for contractor appeals of nonrenewals or terminations of contracts.
- Subpart O—Procedures for imposing intermediate sanctions.

Each of these subparts is discussed below in section II of this preamble. Sections III and IV consist of separate discussions of provisions of the part 422 regulations that specifically concern M+C MSA plans and M+C private fee-for-service plans, respectively.

II. Provisions of the Interim Final Rule

A. General Provisions—Subpart A

1. Overview

Subpart A begins with a brief section (§ 422.1) that specifies the general statutory authority for the ensuing regulations and indicates that the scope of part 422 is to establish standards applicable to the M+C program. Under § 422.2, we then set forth definitions for terms used in part 422 that we believe need clarification. These definitions provide the generally applied meaning for terms that are used throughout part 422. Where necessary, we have included in specific subparts of part 422 definitions for terms used primarily in those subparts. In § 422.4, we define the three different types of M+C plans, consistent with section 1851(a)(2)—M+C coordinated care plans, M+C MSA plans and M+C private fee-for-service plans.

Sections 422.6 and 422.8 then detail the application process for an entity seeking an M+C contract and HCFA's application evaluation procedures.

Section 422.10 adopts, for purposes of the M+C program, the user fee provisions now set forth at § 417.472(h).

2. Definitions (§ 422.2)

For the most part, the definitions presented here are taken directly from the statute or are essentially self-explanatory. Below, we discuss some notable exceptions to this, including cases where we have clarified the exact meaning and context of certain terms. Please keep in mind that the definitions set forth in subpart A reflect general meanings for the terms as they are used in part 422 unless otherwise indicated; the definitions apply strictly for purposes of part 422. For example, the term ''provider'' has a more inclusive meaning under part 422 than it does for other Medicare purposes, as discussed below. Similarly, when we define a term anywhere in part 422 other than in subpart A, it can be assumed that the definition of the term is limited to a specified purpose in the relevant subpart or section. Thus, as specified in the relevant sections of the regulations, the term ''substantial financial risk'' has a different meaning for purposes of the physician incentive provisions under § 422.208 than it does in the PSO provisions under § 422.356.

Benefits and Benefit Categories

In § 422.2, we have defined both the term ''benefits'' as well the different categories under which benefits are provided: basic benefits, additional benefits, mandatory supplemental benefits, and optional supplemental benefits. ''Benefits'' consist of the health care services delivered or covered by an M+C organization. (Note that ''services,'' under the long-standing Medicare definition at § 400.202, encompass medical care, services, and items.) The definition of benefits is relevant both for purposes of the process of determining adjusted community rates (ACRs) for M+C plans and for purposes of a new provision in Part C that ''pre-empts'' State laws relating to ''benefits.''

When we refer to one of the categories under which benefits are provided, however, we generally are referring not only to the actual health services that a beneficiary receives or is eligible to receive, but also to the pricing structure applied to these benefits. For example, the definition of ''additional benefits'' includes both the health care services covered under a plan that are in addition to regularly covered Medicare services, as well as any reductions in premiums or cost-sharing for Medicare covered services. Thus, the amount of deductibles or copayments that an M+C plan enrollee must expend to receive services would fall within the scope of the term ''additional benefits.''

We wish to note that we have defined ''basic benefits'' in this regulation to include *both* the Medicare-covered benefits required under section 1852(a)(1)(A) *and* required ''additional benefits'' under section 1852(a)(1)(B). Both Medicare benefits and required additional benefits are: (1) Coupled together in section 1852(a)(1), in the first paragraph under subsection (a), titled ''Basic Benefits''; (2) benefits that an M+C has an obligation to provide (in contrast to supplemental benefits, which may be provided totally at the M+C organization's discretion); (3) benefits paid for with Medicare trust fund money; and (4) benefits that are covered by the basic premium, if any, that counts towards the limit based on the actuarial value of original Medicare coinsurance and deductible amounts.

For all of these reasons, we have decided to divide benefits into the two categories of the ''basic benefits'' including all required benefits, and ''supplemental benefits,'' including both mandatory and optional supplemental benefits provided at the discretion of the M+C organization. We note that while Congress did not include a ''definition'' of ''basic benefits'' in Part C, it appears to use the term ''basic'' to refer only to the Medicare-covered service package. (See, for example, section 1851(b)(1)(B) or section 1854(e)(1).) Although Congress did not actually include additional benefits in the term ''basic benefits,'' in almost all cases, it coupled these benefits together, and treated them the same. (See sections 1852(a)(1), and 1854(a)(2)(A), (3)(A), (4)(A), and (e)(1).) We accordingly believe that it is appropriate in this regulation to include these two categories together in the definition of ''basic benefits'' that applies for purposes of part 422. We note, however, that where a statutory provision refers only to the Medicare benefit component of our part 422 definition of ''basic benefits,'' we will similarly limit the regulation implementing that provision.

M+C Organization and M+C Plan

The definitions of ''M+C organization'' and ''M+C plan'' set forth in § 422.2 are based on the BBA's use of these terms, which is not always compatible with the way the terms ''organization'' and ''plan'' have been used in the past. In previous HCFA documents, the term ''managed care organization'' frequently has been used interchangeably with the term ''managed care plan'' or ''health plan.'' Section 422.2 addresses this area of potential confusion by clarifying the distinction between an M+C organization and an M+C plan. Succinctly stated, an M+C ''organization'' is an entity that contracts with HCFA to offer an M+C plan; the ''plan'' consists of the specific health benefits, terms of coverage, and pricing structure.

Section 1857(a) specifically states that HCFA contracts with an M+C organization. Thus, for requirements that we would normally think of as contractual requirements, we use the term ''M+C organization.'' In § 422.2 then, an M+C organization is defined as a public or private entity organized and licensed under State law as a risk-bearing entity (with the exceptions of PSOs receiving waivers) that is certified by HCFA as meeting the M+C contract requirements. Under various BBA provisions, the requirements M+C organizations are responsible for meeting include: processing the enrollment and disenrollment of beneficiaries within a plan; transmitting information such as enrollment information and encounter data to HCFA; submitting marketing materials; providing all Medicare-covered benefits and other benefits covered under the contract in a manner consistent with specified access standards; performing quality assurance; creating and carrying out all plan procedures for grievances, organization determinations, and appeals; maintaining necessary records; providing advance directives; establishing procedures related to provider participation; setting medical policies; notifying beneficiaries of any ''Conscience Protection'' exceptions; disclosing physician incentive plans; receiving payment; reporting financial information; paying user fees; making prompt payments to providers; receiving any sanctions invoked by HCFA on any of the organization's plans; and fulfilling other contract requirements as specified in regulation.

Again, in contrast, an M+C plan is merely the health benefits coverage and pricing structure that the organization offers to beneficiaries. An M+C plan may include the basic benefits only (basic benefits include Medicare-covered benefits and additional benefits) or basic benefits combined with mandatory and/or optional supplemental benefits.

An M+C organization may select which providers furnish services under the plan, as long as the benefit package meets all the requirements for access within the area, and outside of the area for specific services. As discussed in detail below, service areas and benefit packages generally are associated with individual plans; uniform premium requirements and the need for an ACR proposal also apply at the plan level.

Service Area

The service area designation of an M+C plan is an important element of the structure and design of a particular plan. A plan's service area—

- Determines the payment rate to the organization for enrollees of the plan, based on the counties included in the service area;
- Affects what benefits will be provided, since benefits and premiums must be uniform under an M+C plan, throughout that plan's defined service area;
- Determines which beneficiaries are able to elect the plan, because organizations are obligated to enroll any eligible resident of the service area who elects the plan; and
- For network plans, is the area in which the plan is required to make covered services available and accessible; and determines the boundaries beyond which the plan assumes liability for urgently needed care and may offer enrollment continuation options.

As explained below, we will exercise discretion in reviewing and approving service areas requested by M+C plans. For network plans, we will use our knowledge of how service areas have been designated in the past in the Medicare managed care program and in the Federally-qualified HMO program, which we have administered since 1986, to ensure availability and accessibility of services. We will attempt to ensure that service areas of M+C network plans are consistent with community patterns of care and/or rating practices—that is, service area designations are not artificially delineated in such a way that usual sources of care, in terms of geographic location, are not available to beneficiaries; or in such a way that the service area designation allows ''gaming'' of the community rate that forms the basis of M+C premiums and benefits, to the disadvantage of Medicare beneficiaries. A nondiscrimination standard will also apply to both network and non-network plans. To the extent possible, we will attempt to ensure a ''level playing field'' among plans operating in the same geographic area (for example, if one plan in an area is subject to the county integrity rule discussed below, a new plan may also be subject to the same standard in determining a new service area). These standards will also be applied in evaluating requests for M+C service area expansions and service area reductions. Consistent with the goals of the new M+C program, we will attempt to maximize the number of choices available to Medicare beneficiaries and maximize the availability of low-cost plans offering additional benefits.

The regulations at § 422.2 provide that an M+C organization may propose a specified service area for each M+C plan, and HCFA will determine whether the proposed area can be approved. The regulatory definition of service area is slightly different from the current service area definition at § 417.401. The latter regulation defines the term geographic area (which we used interchangeably with service area with respect to section 1876 contracts) as ''the area found by the Secretary to be the area in which an HMO is able to deliver the full range of services,'' a definition that was essentially common to both the Medicare program and the Federally qualified HMO program (§ 417.1, ''service area''). The earlier definition emphasizes the role of the Secretary (HCFA) in the designation of service areas, and incorporates one of the standards applicable to network plans (which continue to apply to such plans in these regulations). Statutory references to a service area or geographic area under Medicare, including references in the BBA, do not offer a definition of the term or an indication of how the area is to be determined.

We have modified the wording of the earlier regulatory definition of ''service area'' to recognize that organizations will propose specific areas for M+C plans. Pursuant to section 1856(b)(1), which provides for establishing M+C standards by regulation, and section 1856(b)(2), which provides for basing the standards on standards under section 1876, we have retained our authority to approve or deny service area configurations that organizations propose. This reflects what has been the actual past practice of the agency in administering the Medicare HMO/CMP program and the Federally-qualified HMO program. The new definition also recognizes that service areas designated by organizations for non-network plans are designated for the purpose of determining who is eligible to enroll in the plan.

Consistent with current and past regulatory and statutory standards, we will evaluate proposed service areas of network plans to determine whether covered services are available and accessible, under the standards of § 422.112, to any resident of the area eligible to elect enrollment in the plan. We will also examine the proposed service area of any plan, including non-network plans, to ensure that the delineation of the area does not result in discrimination against beneficiaries through ''gerrymandering'' or ''red-lining'' to deliberately avoid particular areas (e.g., to prevent the enrollment of poorer Medicare beneficiaries, or those known to be in poorer health). An example of such a practice would be an

urban area network plan's exclusion of poorer inner-city areas, leaving obvious ''holes'' in the service area where residents would not have any problem gaining access to care through the plan's providers had the area been included in the proposed service area. Although we would not ordinarily dictate the inclusion of particular areas in the service area of a plan—for example, a multi-county commercial plan could include only some of its counties in a Medicare contract—we would seek to prevent clear cases of discrimination against, or disadvantaging of, particular groups or populations.

Prior to the BBA, contracting HMOs and CMPs (virtually without exception) all had existing, defined service areas prior to entering into a Medicare contract. These were areas in which the entities offered comprehensive health care services to non-Medicare enrollees of the specified geographic area. As noted above, Medicare's statutory language did not clearly define the terms service area or geographic area, but it was assumed that each organization would have a specific service area in which it operated and provided coverage to any enrollee from the community (including any Medicare enrollee). The Medicare premiums and benefits are a function of the community rate of the plan, the rate applicable to any covered group within the community covered by the plan. Hence, until the mid-1980s, we required that the service area for Medicare be the same as the service area for the non-Medicare population. Subsequently, we changed our policy to permit HMOs and CMPs to limit the Medicare service area to a subset of the non-Medicare (commercial) area, breaking the link between commercial service areas and Medicare service areas (though the Medicare premiums and benefits continue to be based on the community rate for the entire non-Medicare community). We applied a ''county integrity'' standard in determining how HMOs could reduce their service areas for Medicare; whole counties could be excluded, but partial counties could only be excluded if the organization operated (for commercial purposes) only in a portion of the county.

Because the BBA provisions on waiver of minimum enrollment and composition of enrollment requirements permit organizations to have M+C plans with no prior enrollment, there will be plans that do not have designated service areas and do not have a commercial service area that can be used as a reference point for the designation of a Medicare service area. In the case of network plans, we would work with such organizations to determine an appropriate service area for the plan's provider network, taking into consideration the patterns of medical care in the community (e.g., where people obtain care, the types of providers available in the community, reasonable travel times to obtain care). We would also use our knowledge of how plan service areas generally have been determined and approved in the past, as well as how other organizations in the same area, or a similar area, have established their service areas. There could be concerns both with a proposed area that is too wide, offering limited availability of services for outlying areas, and with a proposed area that is too small, which would limit choices available to beneficiaries or might raise the concerns discussed above regarding discrimination.

We believe that basing our decisions on community patterns of care and the practices of other organizations in the same area, or in similar areas, is consistent with our past approach to the issue of service area designations, and consistent with the BBA. The BBA requires a similar approach in developing elements of the adjusted community rate for new plans (e.g., 1854(f)(4), referring to ''enrollment experience of other contracts entered into under this part and * * * data in the general commercial marketplace'').

With respect to another issue related to service areas, our policy that permitted HMOs and CMPs under 1876 to vary premium and benefit offerings by county within a service area (the ''flexible benefits'' policy) will no longer apply under M+C. The flexible benefits policy permitted organizations to use non-Medicare revenue to offer extra benefits or reduced premiums (''free benefits'') to residents of a particular county or counties rather than in the entire service area, as long as all Medicare beneficiaries in the entire service received at least the level of benefits required under the statute as determined through the adjusted community rate process. With the requirement that premiums and benefits be uniform throughout an M+C service area, it is not possible to continue the flexible benefits policy. However, an organization may be able to offer multiple plans and propose different service areas for the plans in order to achieve a similar result as the flexible benefits policy. This presents us with an issue of how to deal with the proposals for service areas, or the carving up of existing non-Medicare service areas, when it is done in order to have different premiums and benefits in different counties. In the case of network plans, a carving up of an existing service area, and the offering of multiple plans across what may be a single service area for the non-Medicare population, is only possible if each of the plans with different service areas is able to ''stand alone'' in terms of meeting all the requirements applicable to plans. The designation of multiple service areas in such cases should also be consistent with community practices in patterns of care, and/or consistent with rating practices, and service are designations, for other purchasers.

Except in the case of non-network MSA plans, as discussed below, the fact that Medicare pays different capitation rates by county is not a sufficient reason to establish service areas consisting of individual counties. For example, a staff-model HMO operating in a multi-county area, that has a service delivery network consisting of only one hospital and a group of physicians employed by the organization, cannot designate each county as a separate service area. Although services are accessible and available in each county, we do not believe there is a valid reason to charge different premiums by county, for example, when all Medicare beneficiaries enrolled in the organization will be using the same providers.

On the other hand, some organizations that operate with very large service areas may be justified in breaking up larger service areas for Medicare contracting purposes. This would be similar to what Federally-qualified HMOs do in designating distinct service areas as ''regional components,'' which are sub-areas with an autonomous provider network and with different community rating for the regional component. Some HMOs, although they do not identify distinct service areas, require enrollees to obtain services from a particular subset of providers within the broader network (as Federally-qualified HMOs are permitted to do (see 45 FR 28655 (April 29, 1980)). Some HMOs offer large employers a statewide service area consisting of different provider networks in geographically distinct areas in which there is no crossing of boundaries, or very little crossing of boundaries, to receive services. The large employer may be offered one rate for all areas, but the same HMO may have smaller designated service areas for smaller regional employers, in which different rates apply.

In evaluating proposals requesting approval of multiple service areas in a contiguous geographic area, we would consider the patterns of care in the community; and the rating and service

area practices of the individual organization, of other organizations in the area, and of other organizations in similar areas. The commercial service area will continue to be a reference point in that we would be likely to approve a proposal if what is proposed for Medicare contracting is similar to what is done in the commercial marketplace. Similarly, we would take into consideration any determination, or approval, of service areas by State regulatory bodies.

At a minimum, each proposed M+C service area must be an area in which the full range of covered services are available and accessible to all Medicare enrollees primarily through providers located in the service area. We would also evaluate proposals on the basis of the criteria we discuss above relating to discrimination against, or disadvantaging of, particular beneficiaries in the community. These criteria would also be used in evaluating the proposed service areas of non-network plans. Using the inner-city example, an entity could request an area consisting only of the poorer inner-city area, where residents would be required to pay a relatively high premium, while other areas were charged a much lower premium. We would view this practice as discouraging enrollment within a particular area. Although the statute does not expressly provide for evaluation of service area designations to determine whether they are discriminatory, we believe that it is consistent with statutory requirements relating to discrimination and discouraging enrollment (at 1852(a)(3), with respect to the pricing of mandatory supplemental premiums, and 1852(b), with respect to limiting enrollment based on a health status factor, including claims experience or insurability). We have included the above criteria for service area approval in the definition of ''service area'' in § 422.2.

As noted above, we are providing for a special exception for service areas for non-network MSA plans. In the case of M+C MSA plans, differences in payment rates for a given county affect not just the amount the M+C organization offering the MSA plan is paid, but the amount that is deposited in MSA accounts. (See section III of this preamble.) We have decided that in the case of M+C non-network MSA plans, under which enrollees are not limited to receiving services in a defined area, we will permit M+C organizations to offer a different M+C plan in each county in which they wish to enroll beneficiaries. This would mean that a uniform amount would be deposited in the M+C MSA account of every enrollee in the M+C MSA plan, and the M+C organization could file a separate premium amount for each county to ensure that the proper amount is deposited in accounts in that county.

Emergency and Urgently Needed Services

The definitions of emergency services and urgently needed services in § 422.2 are based on section 1852(d) and thus differ from those in existing § 417.401. In accordance with section 1852(d)(3) of the statute, we are codifying the concept that an ''emergency medical condition'' exists if a ''prudent layperson'' could reasonably expect the absence of immediate medical attention to result in serious jeopardy or harm to the individual. In addition, the new definition of ''emergency services'' includes emergency services provided both within and outside of the plan, while the definition of ''urgently needed services'' continues to encompass only services provided outside of the plan's service area (or continuation area, if applicable), except in extraordinary circumstances such as those discussed below.

Under section 1852(d)(1)(C)(i), M+C organizations are required to pay for nonemergency services provided other than through the organization where the services are immediately required because of unforseen illness, injury or condition, and it is not reasonable given the circumstances to obtain the services through the organization. We believe that except in the rarest and most extraordinary of circumstances, the only situation in which it would not be reasonable to receive nonemergency services through the organization would be when the enrollee is absent from the service area of the M+C plan in which he or she is enrolled. It is possible, however, albeit extremely unlikely, that there might be other situations in which this standard would be met by an enrollee who is in the plan service area.

For example, there could be some temporary disruption of access to the M+C plan's provider network, such as a strike, or possibly some temporary physical impediment to traveling to M+C plan providers that are otherwise readily accessible. Under such circumstances, an individual might not need emergency services, but still may warrant immediate attention. Because we do not believe that we can say that the statutory standard could *never* be met by an individual who is in the plan service area, we believe it is appropriate to provide for an exception in the definition of urgently needed services to the rule that the enrollee be out of area. We are thus providing for such an exception in extraordinary cases in which the network is unavailable or inaccessible due to an unusual event.

Other Definitions

In our April 14, 1998 interim final rule setting forth the definition of a PSO and related requirements, we established under § 422.350(b) a definition for ''health care provider'' that is based on the PSO requirements in section 1855(d)(5). In this interim final rule, we are adopting the identical definition for general purposes of the M+C program. Under this definition, as discussed in greater detail in our April 14 interim final rule (63 FR 18126), the term ''provider'' applies both to individuals licensed or certified by a State to engage in the delivery health care services (such as physicians, nurse practitioners, clinical social workers), as well as to entities engaged in the delivery of health care services (such as hospitals, nursing homes, home health agencies).

Another clarification contained in this subpart involves the definition of ''copayment.'' We have defined copayment as a fixed amount that can be charged for a service. This is to distinguish copayment from ''coinsurance,'' which is a fixed percentage of the total cost of a service that can be charged. Copayments, coinsurance, and deductibles represent the three forms of cost-sharing under a plan.

Finally, we have included a general definition of the term ''balance billing,'' indicating that balance billing refers to an amount billed by a provider that represents the difference between the amount the provider charges an individual for a service and the sum of the amount the individual's health insurer (for example, the original Medicare program) will pay for the service plus any cost sharing by the individual. We note that there is significant variation within both original Medicare and the M+C program regarding the extent to which balance billing is permissible. For example, under original Medicare, no balance billing is permitted for providers of services (such as hospitals and home health agencies), while for nonparticipating physicians, balance billing is permissible only up to the difference between the Medicare allowed amount and the Medicare limiting charge. Different rules apply under original Medicare for other nonparticipating suppliers (such as ambulance or durable medical equipment suppliers, for which there are currently no limits on balance

billing). Similarly, under the M+C program, different balance billing restrictions apply depending on the type of M+C plan and the contracting status of the provider. These restrictions are discussed in detail in the appropriate sections of this preamble, particularly in section IV regarding M+C private fee-for-service plans.

3. Types of M+C Plans (§ 422.4)

The creation of the M+C program allows beneficiaries access to a much wider array of private health plan choices than the existing alternatives to the original Medicare program. Moreover, this new program will enable Medicare to use innovations from the commercial sector that have helped the private market contain costs and expand health care delivery options.

The BBA provides for several different types of M+C plans to be available for beneficiaries. As noted above, these various M+C plans can be classified into three general categories: M+C coordinated care plans, M+C MSA plans (that is, a combination of a high deductible M+C health insurance plan and a contribution to an M+C MSA), and M+C private fee-for-service plans. Within each of these three categories, M+C organizations may offer a variety of plans to Medicare beneficiaries.

Since these are the only legally significant categories of plans under the M+C program, we do not believe it is necessary to define all of the different entities that accept prepaid, capitated payment for delivering health services. Thus, examples of these entities, such as PPOs, HMOs, or health insurance organizations, are not defined for purposes of this regulation. Essentially, all entities that apply to offer an M+C plan must conform to the requirements for either an M+C coordinated care plan, an M+C MSA plan, or an M+C private fee-for-service plan.

M+C Coordinated Care Plans (§ 422.4(a)(1))

Under the M+C program, beneficiaries may choose from among a variety of coordinated care plans. Coordinated care plans include, but are not limited to, HMO plans (with or without point of service options) (HMOs), plans offered by PSOs (as defined in section 1855(d) and in our April 14, 1998 interim final rule), and PPO plans. In addition, certain beneficiaries may be able to choose another type of coordinated care plan, the Religious Fraternal Benefit Society plan, which is defined in section 1859(e).

Except in the case of a PSO granted a waiver under subpart H of part 422, all organizations offering M+C coordinated care plans must meet the State licensure requirements in section 1855 (and § 422.400). Thus, an M+C coordinated care plan must be offered by an entity that is (1) appropriately licensed by the State to bear risk and (2) eligible to offer health insurance or health benefits coverage in each State in which it offers an M+C plan.

In addition, an M+C coordinated care plan must meet the definition of a coordinated care plan set forth in § 422.4. That is, an M+C coordinated care plan is a type of plan offered by an M+C organization that includes a network of providers that are under contract or arrangement with the organization to deliver the benefit package approved by HCFA. The network must be approved by HCFA to ensure that all applicable requirements are met including access and availability standards, service area requirements, and quality standards. A coordinated care plan may include mechanisms to control utilization, such as referrals from a gatekeeper to receive services within the plan, and financial arrangements that offer incentives to providers to furnish high quality and cost-effective care.

Except for PSOs that have obtained a waiver of the State licensure requirement, and thus are subject to the additional requirements set forth in subpart H of part 422, distinctions among HMOs, PSOs, PPOs, and other coordinated care plans are not relevant for the purpose of applying to offer an M+C plan. The distinctions among the various types of coordinated care plans may be relevant for purposes of State licensure. However, for the purpose of an M+C application, we are not concerned with what type of coordinated care plan an applicant intends to offer. In fact, an entity may offer an M+C coordinated care plan even though it is not specifically licensed as an HMO, PSO, or PPO. As long as the entity is licensed as a risk-bearing entity in accordance with section 1855 of the statute and the plan being offered meets the definition of a coordinated care plan under § 422.4, the entity does not need to be licensed specifically as an HMO, PSO, or PPO to offer an M+C coordinated care plan.

For example, like an HMO or a PSO, a PPO may offer an M+C plan. Any organization that is licensed as a risk-bearing entity in a State may offer an M+C plan that is structured in the form of a PPO. We are not requiring that an organization applying to offer an M+C PPO plan be operating as a PPO in the non-Medicare marketplace. In that sense, the BBA imposes a distinct change from prior law, because it does not require that organizations with Medicare prepaid health plan contracts meet certain conditions imposed on their structure and their commercial business. Under section 1876, a PPO generally could not obtain a Medicare risk contract because most PPOs have members that are enrollees of an indemnity insurance product, and would not meet the requirements under section 1876 to be an ''eligible organization'' entitled to contract under that section. The BBA only requires that an organization be providing health benefits and insurance to enrollees (regardless of whether on an indemnity or prepaid, capitated status) and that it be licensed by the State as a risk-bearing entity.

The majority of the PPOs that are currently operating are plans being offered by State-licensed indemnity carriers or State-licensed HMOs. However, where the State does license the PPO as a risk-bearing entity, the PPO may be eligible to become an M+C organization in and of itself. Conversely, where the State does not allow the PPO to bear risk, the PPOs in those States would not be eligible to become an M+C organization on their own. These PPOs that are not allowed to bear risk may partner with a licensed risk-bearing entity or contract with a licensed risk-bearing entity to ''rent out'' their PPO network of providers. Consistent with our policy of deferring to the State as to which entities constitute licensed risk-bearing entities eligible for the M+C program, HCFA will defer to the State in terms of whether the PPOs can accept partial capitation from the licensed indemnity carrier or licensed HMO.

An entity offering a PPO plan must still comply with the requirements in 1854(e), which limit enrollee financial liability under a PPO plan in the same manner that liability is limited under an HMO plan or any other type of M+C coordinated care plan. That is, the sum of the premium for basic benefits and the actuarial value of all out-of-pocket expenses for such benefits (including the actuarial value of all cost-sharing for non-participating providers in a PPO) cannot exceed the actuarial value of the deductibles and coinsurance in original fee-for-service Medicare. Therefore, if a PPO expects a high level of utilization of non-participating providers, it must have a very low premium or it must have a significantly reduced level of cost-sharing for such services.

Religious Fraternal Benefit Society Plans

One specific type of coordinated care plan authorized by the BBA is a religious fraternal benefit society plan

(RFB plan), which is defined in section 1859(e). An RFB plan is an entirely new type of plan that may be offered under the M+C program.

As with the other types of coordinated care plans, an entity offering an RFB plan must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers an M+C plan. Essentially, an RFB society must meet the state licensing requirements outlined in section 1855. As discussed above, the States define the criteria for licensure, including any fiscal solvency standards that apply.

Also, an organization offering an RFB plan under the M+C program must do more than merely pay health care claims on behalf of their beneficiaries. Rather, RFB plans that constitute M+C coordinated care plans must meet the definition of a coordinated care plan included in this regulation. That is, they must have a network of health professionals and meet the applicable access, availability, service area, and quality assurance requirements.

Section 1859(e) defines and describes the requirements for RFB plans. Section 1859(e)(2) describes an M+C RFB plan as a coordinated care plan that: (A) Is offered by a religious fraternal benefit society only to members of the church, convention, or affiliated group; and (B) permits all members to enroll without regard to health status-related factors. Section 1859(e)(3) states that the RFB plan must be offered by a religious fraternal benefit society that: (A) is described under section 501(c)(8) of the Internal Revenue Code and is exempt from taxation under section 501(a) of that Act; (B) is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches; (C) offers, in addition to an M+C religious fraternal benefit society plan, at least the same level of health coverage to individuals not entitled to Medicare benefits who are members of such church, convention, or group; and (D) does not impose any limitation on membership in the society based on any health status-related factor.

Section 501(c) of the Internal Revenue Code generally describes the rules applicable to those organizations which are not subject to Federal income tax under section 501(a) of the code. Section 501(c)(8) describes one type—fraternal beneficiary societies, orders or associations that (a) operate under the lodge system for the exclusive benefit of a Fraternity itself operating under the lodge system; (b) provide for the payment of life, sick or accident or other benefits for the members of such society or association or their dependents.

RFB Plans have two distinguishing factors from other types of M+C coordinated care plans. The first is that RFB plans are allowed to limit their enrollment to members of the church. Section 1859(e)(1) indicates that a religious fraternal benefit society offering an M+C plan may restrict the enrollment of individuals in the plan to individuals who are members of the church, convention, or group with which the society is affiliated.

In addition to this ability to limit enrollment strictly to members of the church, RFB plans are distinct from other M+C coordinated care plans in that RFB plans may be subject to possible payment adjustments to ensure an ''appropriate payment level.'' Specifically, section 1859(e)(4) indicates that the Secretary shall provide for such adjustment to the payment amounts otherwise established under section 1854 as may be appropriate to assure an appropriate payment level, taking into account the actuarial characteristics and experience of such individuals.

M+C MSA Plans (§ 422.4(a)(2))

The definition of an M+C MSA plan, as well as other requirements that apply solely or in a different manner to M+C MSA plans, are discussed in full in section III. of this preamble. Note that in section III.K. of this preamble, we solicit letters of intent from organizations that intend to offer M+C MSA plans to Medicare beneficiaries and/or to serve as M+C MSA trustees.

M+C Private Fee-For-Service Plans (§ 422.4(a)(3))

The definition of an M+C private fee-for-service plan, as well as other requirements that apply solely or in a different manner to M+C private fee-for-service plans, are discussed in full in section IV of this preamble.

Multiple Plans (§ 422.4(b))

Section 422.4(b) establishes that an M+C organization may offer multiple plans, including plans of different types, under a single contract with HCFA, provided that the organization is licensed or approved under State law to offer the applicable types of plans. We believe that this policy should prove to be less administratively burdensome for both prospective M+C organizations and for HCFA than other alternatives, such as requiring separate contracts between HCFA and an M+C organization for each plan, or type of plan, being offered by the organization. We also specify under this section that if an M+C organization has received a waiver of the licensing requirement to offer a PSO plan, the waiver does not apply to the licensing requirement for other types of plans. Other issues associated with the ability of an M+C organization to offer multiple plans under a single contract with HCFA are discussed below, in the section of the preamble that deals with the contract requirements contained in subpart K of part 422.

4. Applications (§§ 422.6 and 422.8)

Sections 422.6 and 422.8 set forth the application requirements for entities seeking to contract with HCFA to offer M+C plans, as well as HCFA's application evaluation procedures. For the most part we have retained the contracting requirements from §§ 417.143 and 417.144 as authorized by section 1856(b)(2). This section of the law allows HCFA to use past contracting standards applied to contracts under section 1876 or to create new standards as needed to implement the M+C program. The application requirements and evaluation procedures are almost identical to the current application procedures.

The primary change to our previous process is the additional requirement that organizations wishing to contract with HCFA must submit documentation of their appropriate State licensure, or submit documentation of State certification that the entity is, in fact, able to offer health insurance or health benefits coverage meeting State fiscal solvency standards and authorized to accept prepaid capitation for providing, arranging, or paying for comprehensive health care services. (Entities meeting the definition of a PSO can be exempted from this requirement if they meet conditions for a waiver, which can be granted by HCFA—see subpart H of part 422.) This requirement is necessitated by the fact that HCFA will no longer have primary responsibility for determining the fiscal solvency of new contractors. We intend to rely for the most part on State certification to insure that the entities that we contract with are indeed fiscally solvent and have the ability to handle and afford risk payments for health care coverage, although we will if necessary ''look behind'' State certifications for validation purposes.

In one addition to existing rules, § 422.8(b) specifies that HCFA may deny an entity's application to offer an M+C plan if the entity has failed to complete a corrective action plan during the term of its previous contract with HCFA, regardless of whether the contract was under the section 1833, 1876, or the new Part C provisions of the law. We

believe that this provision explicitly ensures that the proven performance problems of entities that apply to contract with HCFA under the M+C program are taken into consideration in the application evaluation process.

5. User Fees (§ 422.10)

The last section of subpart A contains regulations implementing the user fees provided for in section 1857(e)(2). Section 1857(e)(2) directs the Secretary to collect user fees from M+C organizations, with each paying its pro rata share, for the purpose of paying for costs associated with enrollment and information activities under section 1851 and subpart B, and counseling and assistance programs under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 103–66).

Under section 1876(k)(4)(D), the user fees provided for in section 1857(e)(2) apply in 1998 to HMOs and CMPs with risk contracts under section 1876. On December 2, 1997, we published regulations in § 417.472(h) implementing the user fee authority in section 1857(e)(2), and setting forth a methodology for determining an organization's ''pro rata share'' of these fees. (62 FR 63669).

In this interim final rule, we are simply adopting at § 422.10, for purposes of the M+C program, the user fee provisions now set forth at § 417.472(h). Our reasons for adopting the methodology reflected in these regulations are set forth in the preamble to the December 2, 1997 rule. We intend to respond to comments received on the December 2 interim final rule, as well as comments on this rule, in a future rulemaking document.

B. Eligibility, Election, and Enrollment

1. Eligibility to Elect an M+C Plan (§ 422.50)

Section 1876 background: The provisions that have in the past applied to managed care entities (and continue to apply until these entities become M+C organizations) are in section 1876 and part 417 of this chapter. Section 1876(d) provides that Medicare beneficiaries who are entitled to benefits under Part A and enrolled in Part B, or enrolled under Part B only, except those with ESRD, residing in the service area of the plan are eligible to receive all their Medicare benefits through an HMO or CMP that has a contract with HCFA. Regulations at § 417.423(b) excluded beneficiaries who elect hospice care from enrolling in an HMOs or CMPs as long as the hospice election remains in effect. Existing regulations at § 417.460(f) require that HMO or CMP disenroll individuals who move out of their geographic areas, except that § 417.460(f)(2) allows enrollees to remain enrolled in an HMO or CMP under the following circumstances: (1) During a temporary move from the service area for up to 90 days, or (2) during a move to a new area for as long as 1 year if the HMO or CMP has elected to offer this option under § 417.460(f)(2).

a. Eligibility. The BBA established a new section 1851(a) that includes the eligibility criteria an individual must meet in order to enroll in an M+C plan, as defined in § 422.4. Accordingly, except as discussed below at section B.1.b. regarding the transition of Part B only individuals, § 422.50 states that individuals who are entitled to Part A and enrolled in Part B are eligible to enroll in an M+C plan. These individuals are referred to as ''M+C eligible individuals.''

Individuals with end stage renal disease (ESRD) are not permitted to be new enrollees of an M+C organization offering an M+C plan. Section 1851(a)(3)(B) excludes individuals with ESRD from enrolling in an M+C plan generally, but provides that an individual who develops ESRD while an enrollee in an M+C plan may ''continue to be enrolled'' in that plan. For purposes of this provision only we are considering individuals who are enrolled in a private health plan offered by the M+C organization to have been enrollees of the M+C plan when they developed ESRD. In section 422.50(a)(2), therefore, we provide that an individual who develops end-stage renal disease while enrolled in an M+C plan, or in a private health plan offered by the M+C organization offering an M+C plan, may continue to be enrolled in the M+C organization as an M+C plan enrollee.

We take this position because we believe that Congress intended in section 1851(a)(3)(B) to permit individuals with ESRD who are enrolled with an M+C organization to remain enrolled with that organization. If an individual develops ESRD as an enrollee of the organization *after* becoming Medicare eligible, he or she clearly would be permitted under section 1851(a)(3)(B) to remain enrolled with the organization. We do not believe that enrollees of an M+C organization should be penalized because they develop ESRD prior to becoming Medicare eligible rather than after. This position is consistent with our existing policy implementing a similar ESRD exclusion under section 1876, and therefore is supported by section 1856(b)(2), which provides for the retention of ''standards established under section 1876 to carry out analogous provisions of such section.''

We are not continuing the § 417.423(b) exclusion policy on hospice; individuals who elect hospice coverage may elect an M+C plan. Unlike ESRD patients, individuals who elect hospice care are not specifically excluded from participating in the M+C program. In fact, section 1853(h) contains special rules for M+C organizations that enroll hospice patients.

Section 1851(b) states that, except as the Secretary may otherwise provide, individuals must live in the geographic area served by the M+C plan in order to enroll in that plan. We have exercised the discretion provided in this provision to provide that those individuals converting from health plans in which they were enrolled prior to Medicare entitlement who reside out of the plan's service area may also continue enrollment in the M+C organization if they reside in the continuation area of the plan.

An M+C organization must disenroll beneficiaries who permanently move from the service area, unless the plan has chosen to provide a continuation of enrollment option in the area to which the enrollee moved, as allowed in section 1851(b)(1)(B) and the enrollee chooses to remain with the plan. We discuss continuation of enrollment in detail in section b.2., ''Continuation of Enrollment.'' Section 4002 enrollment transition for 1876 risk contracts.

Section 1876 risk contracts cannot be renewed for a contract year beginning on or after January 1, 1999. Current risk contractors that remain in compliance with current standards and that demonstrate compliance with new requirements established by this regulation will be able to transition into the M+C program by entering into an M+C contract, as an M+C organization, with a contract effective date of January 1, 1999.

Section 4002(c) of the BBA provided for a seamless transition of enrolled membership. An individual who is enrolled on December 31, 1998 with an eligible organization under section 1876 shall be considered to be enrolled with that organization on January 1, 1999 under the M+C program if that organization has a contract under Part C of title XVIII for providing services on January 1, 1999, unless the individual has disenrolled effective on that date.

In addition, section 4002(b) provides that an individual who is enrolled in Part B only and is enrolled in an eligible organization with a risk-sharing contract under section 1876 on December 31, 1998, may continue to be enrolled in the

organization in accordance with our regulations. This means that on January 1 there will be a small population of ''grandfathered Part B only'' enrollees retained in organizations formerly with risk contracts that now hold contracts under the M+C program. However, this is a one time opportunity, and an individual who is enrolled in Part B and not entitled to Part A and who disenrolls from the M+C organization is not eligible to elect a plan offered by another M+C organization.

In summary, we are interpreting the statute to allow an individual to transition enrollment from the 1876 program without regard to location of residence or whether the individual has end-stage renal disease and to choose to enroll in any plan offered by the M+C organization into which they are transitioning.

2. Continuation of Enrollment (§ 422.54)

As stated previously, section 1851(b)(1)(B) allows M+C organizations to offer enrollees the option of continued enrollment in the M+C plan when enrollees leave the plan's service area to reside elsewhere, we have to interpieted this to mean on a permanent basis.

M+C organizations that choose the continuation of enrollment option must explain it in marketing materials and make it available to all enrollees in the service area. Enrollees may choose to exercise this option when they move or they may choose to disenroll.

Before an M+C organization may offer a continuation of enrollment option to Medicare beneficiaries, the organization must obtain HCFA approval of the continuation area, its marketing materials, and the organization's assurances that it will meet access requirements. Under section 1851(b)(1)(B), the organization must provide enrollees with reasonable access within the continuation area to the Medicare covered benefits described in section 1852(a)(1)(A).

The payment rate at which the M+C organization will receive payment from HCFA will be based on the rate and adjustment factors that correspond to the beneficiary's permanent residence. The M+C organization must, at a minimum, provide or arrange for the provision of Medicare covered benefits in the continuation area as described in the first sentence of § 422.100(b)(1), and the plan must meet access and cost-sharing requirements for all basic benefits.

Because the rate that we pay to M+C organizations includes amounts that ordinarily must be used to provide additional benefits (see preamble for subpart G), we believe that M+C organizations should be required to provide additional benefits in the continuation area. As noted above, however, section 1851(b)(1)(B) requires only that Medicare benefits be provided to continuation enrollees. We accordingly are considering a legislative proosial to require M+C organizations to provide all services in section 1852(a)(1), including required additional benefits under section 1852(a)(1)(B).

Section 1851(b)(1)(B) requires that ''reasonable access'' be provided in the continuation area, and that enrollees be subject to ''reasonable cost-sharing.'' We are requiring that M+C organizations satisfy the access requirements in § 422.112, and provide services either through written agreements with providers or by making payments that satisfy the requirements in § 422.100(b)(2).

We are defining ''reasonable cost-sharing'' in the continuation area to be limited to (1) the cost-sharing amounts required in the M+C plan's service area (in which the enrollee no longer resides) if provided by contract providers; (2) the cost-sharing amounts required by the continuation area plan if provided through agreements with another M+C plan; or (3) the amount for which a beneficiary would be liable under original Medicare if noncontracting providers furnish the services.

We have included two items in these regulations that reflect our prior experience with similar situations. They are: (1) that plans may require prior notification from members of their intention to use the continuation of enrollment option, but this requirement must be in their marketing materials, and (2) appeals and grievances in the continuation area must be handled in the same timely fashion as in the service area, but the ultimate responsibility for the appropriate handling of appeals and grievances is with the organization that is receiving payment from HCFA.

3. Limitations on Enrollment in an M+C MSA Plan (§ 422.56)

While most M+C eligible individuals can choose to receive benefits through one of the M+C plans defined in § 422.4, the statute places limitations on eligibility to enroll in M+C MSA plans.

Sections 1851(b)(2) and (b)(3) specifically exclude certain individuals from enrolling in M+C MSA plans. We have specified at § 422.56(b) of this section, that individuals who are enrolled in a Federal Employees Health Benefit program (FEHB) plan, or who are eligible for health care benefits through the Veterans Administration (VA) or the Department of Defense (DoD) may not enroll in an M+C MSA plan. The statute provides that the restrictions on FEHB enrollment may be eliminated if the Director of the Office of Management and Budget certifies to the Secretary that the Office of Personnel Management has adopted polices that will ensure that the enrollment of FEHB participants in M+C MSA plans will not result in increased expenditures for the Federal government. The Office of Personnel Management has indicated to HCFA that they would not be able to certify that FEHB costs would not increase at this time. Under our authority in section 1851(b)(2)(B), we intend to apply the same rules for enrollment restriction to individuals who are eligible for health benefits through the VA and DoD. Additionally, in § 422.56(c) we have incorporated the statutory requirement under section 1851(b)(3) that individuals who are entitled to Medicare cost-sharing under a State plan under title XIX are not eligible to enroll in M+C MSA plans. In addition, an individual who receives health benefits that cover all or part of the annual deductible under an M+C MSA plan may not enroll in an M+C MSA plan.

Note that M+C MSA plans are described in detail in Section III of this preamble.

4. Limited Enrollment Under M+C RFB Plans (§ 422.57)

Section 1859(e)(1) states that Religious Fraternal Benefit Society (RFB) plans may limit the enrollment of individuals to those who are members of the church, convention or group with which the society is affiliated. We have included the restrictions on enrollment in RFB plans at § 422.57.

5. Election Process (§ 422.60)

Under section 1851(c)(1) the Secretary is required to establish a process through which elections in M+C plans are made and changed, including the form and manner in which they are done. In § 422.60, we describe the election process for enrollment with the M+C organization. Where applicable we have included existing rules from 42 CFR § 417.430 with conforming changes.

As stated at § 422.66(a), M+C eligible individuals who wish to elect an M+C plan may do so by filing the appropriate election form with the M+C organization. At § 422.60(a), we specify that M+C organizations must accept without restriction, except as specified in § 422.57 for RFB plans, individuals who enroll in an M+C plan during the

election periods described in section 1851(e)(6) and set forth at § 422.62 of the regulation.

As provided by section 1851(e)(6), and stated at § 422.60(a), and displayed in the following chart, M+C organizations are required to accept enrollments during the initial coverage election period, the annual election period, and special election periods, but M+C organizations are not required to be open for enrollment during open enrollment periods.

WHEN ELECTIONS MAY BE MADE OR CHANGED*

Coverage Election Periods	When: § 422.62	M+C Plans Required to Accept Enrollments: § 422.60	Effective Date of Coverage: § 422.68
Initial Coverage Election Period ...	3 months before entitlement to Part A and Part B.	Yes	1st day of month of entitlement to Part A and Part B.
Annual Election Period	Annually in November	Yes	January 1.
Special Election Period	Starting 2002, if beneficiary moves, plan terminates, etc.	Yes	To Be Determined—depends on situation.
Special Election Period at Age 65	Starting 2002, in first 12 months after initial election of M+C plan.	No—Election is original Medicare	1st day of the month after month of election.
Open Enrollment Periods	Anytime 1998–2001 Jan–Jun 2002 Jan–Mar 2003+.	No—Plans have option of accepting enrollments.	1st day of the month after month of election.

*Refer to referenced regulation text for detail.
Note that different rules apply to M+C MSA plans.

As provided at § 422.306(a)(2) to reflect the requirements in section 1854(a)(1)(B), M+C organizations must submit by May 1 of each year the enrollment capacity of each plan they offer. Section 422.60(b) then provides that if HCFA determines that the M+C plan has a capacity limit, the plan may limit the enrollment of M+C eligible individuals if the plan accepts first those individuals who elected the plan prior to the HCFA determination and then accepts others in a manner that does not discriminate on the basis of health status.

We note that we have not included regulation text to address the last sentence of section 1851(g)(2) regarding ''nonrepresentative'' enrollment. As written, the sentence disallows a capacity limit if enrollment would become substantially nonrepresentative of the Medicare population in the plan's service area, as determined in accordance with regulations of the Secretary. We cannot envision circumstances under which the imposition of a capacity limit on enrollment would by itself lead to an enrollment ''substantially non-representative'' of the Medicare population in an M+C plan's service area. We particularly cannot envision circumstances under which the non-representativeness of enrollment would be so ''substantial'' as to justify possible risks to patient access and quality of services as the result of overloaded capacity. We accordingly are not promulgating regulations at this time implementing the authority in the last sentence in section 1851(g)(2). We invite comments on this provision, and would consider including guidance on this matter in a final regulation based upon comments received.

At § 422.60(c) we indicate requirements for the election form. The form must comply with HCFA instructions regarding content and format, must be completed and signed by the beneficiary (or the individual who will soon be entitled to Medicare benefits), and must include authorization for disclosure and exchange of necessary information between HCFA and the M+C organization. Persons who assist beneficiaries in completing forms must sign the form and indicate their relationship to the beneficiary. The forms must also be filed and retained by the M+C organization.

In general, and as indicated by our requirement that the beneficiary complete and sign the form, we believe that an M+C eligible individual should personally complete and sign any election form or disenrollment request (referenced at § 422.66(b)) whenever possible. If for some reason a beneficiary is unable to sign for himself or herself, we recognize and defer to state laws on who may sign for other persons, which is also the policy in the Section 1876 program.

In § 422.60(d), we specify that an election is considered to have been made on the date it is received by the M+C organization. We believe it is necessary that we define ''when an election is made'' because it is a determining factor in establishing the effective date of M+C plan coverage. Note that HCFA's liability for payment is not as of the election date, but rather, is as of the effective date of coverage. Effective dates of coverage are specified at § 422.68.

We have also set forth at § 422.60(e) a process for handling of forms, including for providing written notification of acceptance or denial in the M+C plan.

6. Election of Coverage Under an M+C Plan (§ 422.62)

Section 1876 background: Section 1876(c)(3)(A)(i) requires that HMOs and CMPs hold an open enrollment period for Medicare beneficiaries of at least 30 consecutive days during each contract year to qualify for a Medicare contract. For Medicare beneficiaries who enroll during the open enrollment period, § 417.450(a)(2) states that the effective date of coverage cannot be earlier than the first month, nor later than the third month, after the month in which HCFA received the information necessary to include the beneficiary in its records. In § 417.450(b), HCFA reserves the option to approve a later month if requested by the organization and the beneficiary. HMOs and CMPs can also offer continuous open enrollment outside of the 30-day period.

In the M+C program under section 1851(a)(1), M+C eligible individuals may elect to receive Medicare benefits under original Medicare or through election of an M+C plan. Section 1851(e) describes the various election periods available to M+C eligible individuals. Many of these provisions allow the individual to ''change the election under subsection (a)(1)'' during these periods. If section 1851(a)(1) were read narrowly, it arguably would only allow an eligible individual to change between original Medicare or the M+C program under Part C. We have taken a broader approach in interpreting section (a)(1) to allow eligible individuals to not only make a change between the original Medicare program and an M+C plan, but also among M+C plans. Therefore, an M+C eligible individual

who changes his or her election may change from an M+C plan to original Medicare, from an M+C plan to another M+C plan or from original Medicare to an M+C plan.

The BBA establishes specific parameters in which elections can be made and/or changed. Individuals who wish to elect an M+C plan or subsequently change their election, must do so during the periods established under section 1851(e). That section requires that elections or changes in election be made during the following periods: The initial coverage election period, continuous open enrollment periods, an annual coordinated election period or special election periods. Note that the Medigap implications of a change of election to original Medicare are discussed at section II.B.12 (Extended Period of Guaranteed Access to Medigap Plans) of this preamble.

a. Initial Coverage Election Period. Section 1851(e)(1) requires that the Secretary specify an initial coverage election period during which an individual who is initially entitled to Part A and enrolled in Part B may elect an M+C plan. The statute further stipulates that if an individual elects an M+C plan during that period, coverage under the plan will become effective as of the first day on which the individual may receive that coverage. We believe that Congress intended that we give a newly eligible individual the opportunity to be enrolled in an M+C plan as soon as he or she would be entitled to actually receive both Medicare Part A and Part B coverage.

In other contexts, we have interpreted the concept of ''entitled'' to mean that an individual has met all of the necessary requirements for a benefit (that is, is eligible for the benefit), and has actually applied for and been granted coverage. An individual is considered to be ''enrolled'' under section 1837, on the other hand, when he or she has applied for Part B coverage (or is deemed to have applied). Under some situations, an individual may apply for or be deemed to have applied for Part B before he or she is actually entitled to receive coverage. For example, if an individual applies for Part B coverage and becomes ''enrolled'' after he or she reaches age 65, the individual may not actually be entitled to Part B coverage under section 1838 until one or several months after the month of application and enrollment. If we were to interpret section 1851(e)(1) to give effect to an M+C plan election when an individual has only enrolled in Part B, he or she could be entitled to the benefits of the M+C plan before actually being entitled to Medicare Part B coverage. In order to avoid such a result, we have interpreted ''enrolled'' in Part B as ''entitled'' to Part B.

We believe our interpretation is consistent with section 1851(e)(1), which requires the Secretary to specify an initial coverage election period that would result in coverage under the plan becoming effective as of the first day on which the individual may receive that coverage.

In establishing the initial coverage election period we considered the statutory process of entitlement to Part A and enrollment in Part B. Section 226 of the Act provides that individuals who are age 65 and entitled to retirement benefits under title II or the Railroad Retirement Board Act and those who are under age 65 and have been entitled (or deemed entitled) to disability benefits under title II or the Railroad Retirement Board Act for 24 months shall be entitled to Part A under the Medicare program and eligible to enroll in Part B. Part A coverage is effective the month an individual attains age 65, or the 25th month he or she is entitled to disability benefits. If an individual is entitled to disability or retirement benefits at least 3 months before reaching age 65 or, in the case of a disabled individual, three months before the 25th month in which he or she is entitled to disability benefits, the individual is deemed enrolled in Part B at that time. Under section 1838, Part B is effective with the month an individual reaches age 65 or in the 25th month he or she is entitled to disability benefits.

In order for an individual to have coverage under an M+C plan effective as of the first day on which the individual may receive such coverage, the individual must elect an M+C plan before he or she is actually entitled to Part A and Part B coverage. We have therefore defined the initial coverage election period as the 3-month period that begins 3 months prior to the month the individual is first entitled to both Part A and Part B and ends the last day of the month preceding the month of entitlement.

This approach also permits individuals who do not enroll in Part B at initial eligibility (i.e. at age 65 or in the 25th month of disability entitlement) to elect an M+C plan at the time of subsequent enrollment in Part B. Section 1837(i) provides for a special enrollment period for individuals who defer enrollment in Part B because they are covered under a group health plan based on their own employment or that of a spouse (in the case of the disabled, the employment may be that of any family member). Enrollment in Part B may occur during any month the individual is covered under the group health plan based on current employment or during the 8-month period that begins the first full month the individual is no longer covered under the group health plan based on current employment. Under section 1838(e), Part B coverage is effective the first day of the month the application is filed or, at the individual's option, the first day of any of the following three months when enrollment occurs while the individual is covered under the group health plan based on current employment or during the first full month when not so covered. Therefore, an individual may file an application for Part B up to three months in advance of entitlement. Consequently, individuals who enroll in Part B during the special enrollment period may elect an M+C plan during the 3-month period prior to entitlement to Part B.

Additionally, section 1837(e) allows individuals who fail to enroll for Part B during their initial enrollment period (3 months before they are entitled to Part A or within 3 months after the month they are entitled to Part A) to enroll for Part B during a general enrollment period, which runs from January through March of every year, with coverage effective July 1 of the year of enrollment. In this case, the Part B application may be filed up to 6 months in advance of the month of entitlement. (Individuals who enroll in a general enrollment period are subject to an increased premium under section 1839(b), measured by the length of the delay in enrollment.)

In order to be consistent with the 3 month periods that can occur between timely enrollment for Part B and actual entitlement in existing sections of the Medicare statute, we have limited the period during which an individual may elect an M+C plan to the 3-month period prior to actual entitlement to Part B. We believe that this correlation with the 3-month period will be administratively more efficient than a shorter or longer time period.

b. Annual Coordinated Election Period. Section 1851(e)(6) establishes that organizations offering M+C plans in January, 1999 must open enrollment to Medicare beneficiaries in November, 1998. In addition, section 1851(e)(3) establishes the month of November of each year beginning in 1999 as the annual coordinated election period.

During the month of November, an M+C eligible individual may elect an M+C plan or change his or her election. Thus, the section 1876 requirement that plans be open any 30-day period is replaced by a requirement that plans

have to be open for enrollment during the month of November.

c. Open Enrollment Periods. Section 1851(e)(2) establishes open enrollment periods during which M+C eligible individuals may elect an M+C plan, if it is open to new enrollees, or change their elections. M+C individuals may not, however, as provided in section 1851(e)(5), elect an M+C MSA plan during open enrollment periods.

Note that as provided by section 1851(e)(6) and stated at § 422.60(a)(2), M+C organizations may, but are not required, to offer continuous open enrollment during open enrollment periods. This is similar to the section 1876 policy which also allowed, but did not require, continuous open enrollment outside of a 30-day period.

Section 1851(e)(2)(A) establishes that at any time during calendar years 1998 through 2001, there will be no limit on the number of elections or changes that an M+C eligible individual can make.

Section (e)(2)(B) establishes the first six months of 2002, (January through June) as the open enrollment period for that year. An M+C eligible individual may elect an M+C plan or change his or her election, but only once during the first six months of the calendar year.

Section (e)(2)(C) establishes the first three months of each year (January through March) beginning 2003, as the open enrollment period. An M+C eligible individual may elect an M+C plan or change his or her election, but only once during the first three months of the calendar year.

Section 1851(e)(2)(B)(i) allows that an individual who becomes an M+C eligible individual in 2002 and elects an M+C plan or original Medicare, to change that election once during the first 6 months of M+C eligibility in 2002. Beginning in the year 2003 and thereafter, a newly eligible individual who has made an election may change that election once during the first 3 months of M+C eligibility in that year. Consequently, those who become M+C eligible individuals late during the year may not have a full 6-month or 3-month open enrollment period. For example, an individual who becomes eligible in August 2002 has an open enrollment period of 5 months, August through December. The sixth month, January, does not occur during 2002 and cannot qualify as part of the open enrollment period.

The limit to one change during the open enrollment periods in the first six months of 2002 and the first three months of subsequent years does not apply to changes in elections that an individual makes during an annual coordinated election period or during a special election period.

In § 422.62, paragraphs (a)(4)(ii) and (5)(ii), we have interpreted the 6 and 3 month periods ''in which the individual is an M+C eligible individual'' in section 1851, paragraphs (e)(2)(B)(i) and (e)(2)(C)(i), as the periods that begin with the month the individual is first ''entitled to both Part A and Part B.'' The statute defines ''eligible for Medicare+Choice'' as eligible for Part A and enrolled in Part B, a definition that we have reflected in § 422.50(a)(1); however, this definition could cause problems for newly eligible individuals during the open enrollment period.

For example, individuals who are newly eligible for M+C in the year 2002 under section 1851(e)(2)(B) will have 6 months, beginning with their eligibility for M+C, to change their election. If we start counting this period from the time individuals enroll in Part B, some will have little or no opportunity to change. Some of these individuals may not actually be entitled to receive benefits for a delayed period, which can be up to 6 months after they have enrolled if they have enrolled during a general election period. Hence, the opportunity to change could have no meaning, with the open enrollment period expiring before the individuals have actually received any M+C coverage.

d. Special Election Periods. Section 1851(e)(4) establishes special election periods beginning in 2002, during which M+C eligible individuals may disenroll from an M+C plan or elect another M+C plan. Special election periods are available if: (1) The service area or continuation area is reduced or the plan terminates or is terminated in the area in which the individual resides; (2) the individual moves out of the plan's service area and the plan does not offer, or the individual does not elect, the continuation of enrollment feature, or there is some other change of circumstances specified by HCFA; (3) the individual demonstrates to HCFA, in accordance with guidelines established by HCFA, that the M+C organization offering the plan substantially violated a material provision of its contract with regard to the individual or the organization, its agent, representative, or plan provider materially misrepresented the plan's provisions in marketing the plan to the individual; or (4) the individual meets such other exceptional conditions specified by HCFA.

The last paragraph in section 1851(e)(4) provides that, effective January 1, 2002, an individual who, upon first becoming eligible for benefits under Part A at age 65, enrolls in an M+C plan (other than an M+C MSA plan), may discontinue the election and elect original Medicare at any time during the 12 month period beginning on the effective date of the M+C election. We have interpreted this provision to apply to individuals who elect an M+C plan (other than an M+C MSA plan) during the initial enrollment period, as defined under section 1837(d), that surrounds their 65th birthday. This period begins 3 months before and ends 3 months after the month of an individual's 65th birthday. We believe that this interpretation fulfills the intention of the statute, which is to provide this special election period to individuals who, upon turning 65 and first becoming entitled to Medicare, elect an M+C plan. Our interpretation takes into account the fact that many, if not most, individuals will be making an election during an initial enrollment period, rather than during the month that they turn 65.

e. Special Enrollment and Disenrollment Rules for M+C MSA Plans. Section 1851(e)(5) establishes special rules for individuals enrolling in M+C MSAs. M+C eligible individuals may elect the M+C MSA option only during an initial coverage election period or during November of any year, beginning in 1998. M+C MSA enrollees may discontinue their election only during November of 1998, during annual coordinated election periods in November of each subsequent year, and during special election periods described in the first sentence of section 1851(e)(4). Individuals who elect an M+C MSA for the first time during the annual coordinated election periods that begin in November of 1999 may revoke their election if they do so before December 15 of the year in which they make the election, i.e., before the M+C MSA coverage begins. M+C MSA plans are described in detail at the end of this preamble.

7. Information about the M+C Program (§ 422.64)

Once these regulations are effective and M+C plans are approved by HCFA, eligible Medicare beneficiaries will be able to choose to receive their Medicare benefits from a new array of health care options. New options will include coordinated care plans such as Health Maintenance Organizations, Preferred Provider Organizations, Provider Sponsored Organizations, as well as Private Fee for Service Plans and Medical Savings Accounts. Medicare beneficiaries will still be able to choose to remain in original Medicare. These choices are designed to offer Medicare beneficiaries a marketplace of options

similar to those available to the non-Medicare population.

Under section 1851(d)(2), the Secretary is obligated to mail an ''open season notification'' at least 15 days before the beginning of each annual coordinated election period to each M+C eligible individual residing in an area and, to the extent practicable, to a newly eligible individual not later than 30 days before the individual's initial coverage election period. The notice must include certain general information listed in section 1851(d)(3) and a list of plans and certain plan comparisons as described in section 1851(d)(4). Section 1851(d)(1) requires that HCFA provide for activities to broadly disseminate information to beneficiaries and prospective beneficiaries on their coverage options under M+C, and section 1851(d)(5) requires HCFA to maintain a toll-free line for M+C inquiries and an Internet site through which individuals can obtain electronic information.

To promote informed choice, HCFA will provide access, via the Internet and through distribution of print materials, to information about original Medicare and M+C options. In accordance with section 1851(d)(3) and reflected in § 422.64(c), HCFA will provide general information to M+C eligible individuals with respect to benefits available under Part A and Part B of original Medicare, including covered services, beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts, including any beneficiary liability for balanced billing. Such general information will also include instructions on how to exercise election options under M+C; procedural rights including the grievance and appeals procedures for original Medicare and M+C and the individual's right to be protected against discrimination based on health status related factors under section 1852(b), including the fact that an M+C organization may terminate its contract, refuse to renew its contract, or reduce the service area included in its contract and the effect this may have on the individuals enrolled in the M+C plan. Finally, a general description of the benefits, enrollment rights, and other requirements applicable to Medicare supplemental policies under section 1882, including Medicare Select, will be included.

Under section 1851(d)(4) and reflected in § 422.64(c)(6), HCFA will also provide information to M+C eligible individuals comparing M+C plan options, including the benefits covered under the M+C plan; covered services beyond those provided under original Medicare; and beneficiary cost-sharing including maximum limitations on out-of-pocket expenses and, in the case of an MSA plan or M+C private fee-for-service plan, differences in cost-sharing, premiums, and balance billing as compared to other M+C plans and whether the organization offering the plan includes mandatory supplemental benefits in addition to its base benefit package or offers optional supplemental benefits and the premiums and other terms and conditions for such coverage. The M+C monthly basic beneficiary premium and M+C monthly supplemental beneficiary premium, if any for the plan or, in the case of an MSA plan, the M+C monthly MSA premium, will also be included. M+C eligible individuals will also be informed about the extent to which they may obtain benefits through out-of-network health care providers; the extent to which they may select among health care providers and the types of providers participating in the plan's network. M+C eligible individuals will be informed of the M+C organization's coverage of emergency and urgently needed care, service area of the plan, and, to the extent available, M+C plan quality and performance indicators.

The information comparing plan options is crucial to empowering beneficiaries with the knowledge that will help them evaluate M+C options and make informed decisions based on their individual needs. We wish to make clear that our provision of comparative data is intended neither to encourage or discourage beneficiaries from choosing one health care plan over another nor to favor a choice of an M+C plan over original Medicare.

We invite the public to comment or to provide specific guidance on the types of information that should be made available to beneficiaries. Once we have worked out what specific information we will require within the above categories, we will post these at our Internet site.

The Internet site, www.Medicare.gov, is a Medicare beneficiary-centered consumer website designed to provide a broad array of information on program benefits, health system performance, health care choices, healthy behaviors and health promotion. This site will be continuously improved to meet the mandate in section 1851(d)(2)(C) that we provide information in a style and format that is easy to understand. If necessary, we will publish regulations and allow for OMB review, pursuant to the requirements of the Paperwork Reduction Act of 1995.

HCFA's ''Medicare Compare,'' the Managed Care Plans Comparison Database, will be available on the Internet for public use. ''Medicare Compare'' provides a wealth of information on health care plans, allowing users to ''comparison shop'' for plans. Users can look up information in different areas, by state, county or zip code. They can also compare costs for premiums and types of services offered. The information in the database will be updated quarterly. Plan specific quality performance measures from the HEDIS information set and the Consumer Assessment of Health Plans Survey (CAHPS) will be incorporated into information provided to beneficiaries once the data and results have been validated and determined to be accurate and reliable. HCFA is committed to using a public process to determine information and data specifications, including the details of what information will need to be collected and the methods of collection to determine the remaining unspecified data elements that organizations are required to submit. HCFA will work collaboratively with organizations involved with quality and performance standards and measurements, including performance measurement experts, public and private purchasers, and beneficiary representatives in this process. In addition, HCFA will hold public meetings to invite interested parties to comment and provide input in the process of determining the data specifications for additional performance information, e.g., data about appeals or health outcome measures. Finally, HCFA will publish a notice regarding plan data elements to be collected and a summary of public processes used to determine the data elements in question and this document would be available at the discretion of the requestor. Educational information will be made available on the Internet site to prepare consumers on how to use this information when comparing plans and in making decisions about their health care.

In support of efforts to promote informed choice, HCFA will also maintain a toll-free line for M+C information.

Under section 1851(e)(3)(D), we are required to provide in the fall of 1998 for a ''Special Information Campaign'' in the form of an educational and publicity campaign that informs M+C eligible individuals about the availability of M+C plans offered in different areas, and about the election process. Section 1851(e)(3)(C) requires that we provide for a nationally coordinated educational and publicity campaign about M+C plans and the election process in November of each year, beginning in 1999. We may conduct these campaigns

using health fairs, as well as other methods for distributing information.

8. Coordination of Enrollment and Disenrollment Through M+C Organizations (§ 422.66)

a. Enrollment. Section 1851 (c)(1) and (c)(2) provide that individuals who wish to elect an M+C plan may do so through filing an appropriate election form with the organization during an election period specified in section 1851(e), and reflected in § 422.62. Section 1851(c)(1) requires that the Secretary establish a process through which elections in M+C plans are made. Therefore, we reserve the right to develop and provide additional mechanisms for electing an M+C plan. We have provided instructions on how M+C organizations must process elections at § 422.60(e). If necessary, we will publish regulations and allow for OMB review, pursuant to the requirements of the Paperwork Reduction Act of 1995.

b. Disenrollment. Section 1876 background: Under section 1876(c)(3)(B), which covers disenrollment from HMOs and CMPs, a Medicare beneficiary can disenroll from an HMO or CMP at any time. Under the HMO and CMP regulations in § 417.461(a), an enrollee who wishes to disenroll may, at any time, give the organization a signed, dated request in the form and manner we specify. The beneficiary can request a certain disenrollment date, but it can be no earlier than the first day of the month following the month in which the organization receives the disenrollment request. Under section 9312(h) of the Omnibus Budget Reconciliation Act of 1986, Medicare beneficiaries are also permitted to disenroll from an eligible organization under Section 1876 at a local Social Security office.

Section 417.461(b) describes the responsibility of the HMO or CMP to promptly submit a disenrollment notice to HCFA and provide the enrollee with a copy of the request for disenrollment and, in the case of a risk HMO or CMP, an explanation of the date of disenrollment. Section 417.461(c) provides that HMOs and CMPs must reimburse HCFA in cases where a disenrollment notice is not submitted timely to HCFA.

Currently, when an individual enrolls in one HMO or CMP while still enrolled in another, we regard this action as a disenrollment from the first HMO or CMP, and automatically amend our enrollment records to reflect the disenrollment. We do this so that the beneficiary does not have to both submit a disenrollment request to the first HMO or CMP, and an enrollment request to the new HMO or CMP.

To reflect these current policies, § 422.66(b)(1) provides that an individual who wishes to disenroll may change his or her election in the following manner: (i) Elect a different M+C plan during an election period specified in § 422.62 or (ii) submit a signed and dated request for disenrollment to the M+C organization during an election period specified in § 422.62. HCFA also reserves the right to develop and provide additional mechanisms for disenrollments in accordance with section 1851(c). Note that the Medigap implications of a change of election to original Medicare are discussed at section II.B.12 (Extended Period of Guaranteed Access to Medigap Plans) of this preamble.

At § 422.66(b)(2) we specify that a disenrollment request is considered to have been made on the date it is received by the M+C organization. Note that HCFA's liability for payment ends not on the date the disenrollment request is received by the M+C organization, but rather, as of the date of disenrollment. The date of disenrollment is determined at § 422.68 for changes made by enrollees during coverage election periods and at § 422.74 for disenrollments made by M+C organizations.

At § 422.66(b)(3) and (4) we are continuing the § 417.461(b) and (c) requirements for M+C organizations to provide timely notice of disenrollment to HCFA and to provide the enrollee with a copy of the disenrollment request with information on the date of disenrollment and any lock-in requirements of the plan that apply until the effective date of disenrollment. We also state that disenrollment requests must be filed and retained as specified in HCFA instructions.

The regulation also provides that if the M+C organization fails to submit a correct and complete disenrollment notice to us promptly, the M+C organization must reimburse us for any capitation payments it has received after the month in which we would have stopped payment, had the M+C organization met the requirement.

c. Retroactive Disenrollment. Section 1876 background: In the case of section 1876 contractors, HCFA has permitted beneficiaries to be retroactively disenrolled from an HMO or CMP if it determines that there never was a legally valid enrollment, or a valid request for disenrollment was properly made but not processed or acted upon.

In the M+C program, HCFA will continue to consider retroactive disenrollments in cases in which we determine that there never was a legally valid enrollment, or a valid request for disenrollment was made but not processed or acted upon. We have reflected this provision in § 422.66(b)(5).

d. Fee-for-Service Election by Default. Section 1851(c)(3)(A)(i) establishes that newly eligible enrollees who do not choose an M+C plan during the initial coverage election period are deemed to have chosen original Medicare. We have reflected this provision in § 422.66(c).

e. Seamless Continuation of Coverage (Conversions). Section 1876 background: In regulations at § 417.432, an HMO/CMP is required to accept any individual who was already enrolled in the HMO/CMP for the month immediately prior to the month in which he or she was entitled to both Part A and Part B, or entitled to Part B only. HCFA refers to such enrollments as ''conversions'' or ''age-ins.'' The individual's effective month of enrollment in the HMO or CMP as a Medicare enrollee is effective the month in which he or she is entitled to both Medicare Parts A and B, or Part B only.

With the enactment of BBA, a new section 1851(c)(3)(A)(ii) is added to the statute that gives the Secretary discretion to establish procedures under which individuals who are enrolled in a health plan offered by an M+C organization at the time of their initial coverage election periods will ''default'' to or be deemed to have elected an M+C plan offered by the M+C organization, unless these individuals elect a different option. We have chosen not to have individuals default to the M+C plan offered by the organization. At this time we do not have a mechanism in place to capture the information we would need to implement such a process. A default process would require that M+C eligible individuals as well as their relevant health plan information be identified and captured prior to the individual's initial coverage election period. At present, we do not have access to information on which health plans individuals are enrolled in because such plans are private health plans. In addition, we are not given any information if individuals have not previously filed for title II (Social Security) and/or title XVIII (Medicare) benefits.

One option that we may consider would be to specify that M+C organizations which have individuals enrolled in private health plans must notify such individuals 4 months preceding the month in which the individual becomes an M+C eligible individual of their opportunity to ''age-in'' to the M+C plan or to select another option. This would give the individual

the opportunity to select from a range of health care options in a manner that would facilitate seamless continuation of coverage. M+C organizations would be required to transmit to us the necessary plan information for those individuals who are interested in exercising their opportunity to ''age-in''. HCFA would then have the information necessary to ''deem'' or ''default'' M+C eligible individuals into the appropriate M+C plan. We request public comments on this issue and will issue further clarification in the final rule. In the interim, we have retained the conversion of enrollment process described in § 417.432 with conforming changes.

In § 422.66(d) we specify that M+C plans must accept any individual who is enrolled in a health plan (other than an M+C plan) offered by the same M+C organization, during the month immediately preceding the month in which the individual is entitled to both Part A and Part B. Conversion may occur if the individual resides in the service area or continuation area of the plan and regardless of whether an individual has ESRD. We limit conversions to individual in a service area and continuation area in order to ensure that enrollees have access to the full range of services offered by the plan. This policy is also reflected in the section describing eligibility to elect a plan (§ 422.50(a)(2) and (a)(3)). Therefore, an M+C organization's obligation to accept current enrollees extends to enrollees in a service area or a continuation area, or who developed ESRD while enrolled with the organization under a private health plan. Converted beneficiaries who reside out of the plan's service area or who have ESRD cannot, however, later elect to enroll in a plan offered by another M+C organization unless they meet the statutory requirements at sections 1851(b)(1)(A) and 1851(a)(e)(B).

In addition, we allow M+C organizations to reserve vacancies for their plans to accommodate conversions in recognition that M+C organizations must accept conversions. We require the individual who is converting to file an election form in accordance with § 422.60(c)(1). We also stipulate that the M+C organization may not disenroll the individual except under the conditions described in § 422.74.

f. Maintenance of Enrollment. The statute provides at section 1851(c)(3)(B) that an individual who has made an election or is deemed to have made an election is considered to have continued to make that election until the individual changes it or the M+C plan is discontinued or no longer serves the area in which the individual resides. We have stated this rule at § 422.66(e).

9. Effective Dates of Coverage and Change of Coverage (§ 422.68)

Section 1851(f) establishes the effective dates for elections and changes to elections made during the various enrollment periods. Note that the Medigap implications of a change of election to original Medicare are discussed at section II.B.12 (Extended Period of Guaranteed Access to Medigap Plans) of this preamble.

Section 1851(f)(1) states that an election made during the initial coverage election period will take effect on the date the individual becomes entitled to Part A and enrolled under Part B, but gives the Secretary discretion to interpret this provision in a manner, consistent with section 1838, that prevents retroactive coverage. We are interpreting ''enrolled in Part B'' as ''entitled to Part B'' in order to avoid retroactive coverage in an M+C plan that an individual might receive after enrolling in Part B but prior to the time the individual is actually entitled to Part B benefits. Therefore, we have established that an election made during the initial coverage election period is effective the first day of the month of entitlement to both Part A and Part B.

Under section 1851(f)(3), an election or change of election made during an annual coordinated election period is effective the first day of the following calendar year. We have reflected this provision in § 422.68(b).

Under section 1851(f)(2), an election or change of election made during an open enrollment period is effective the first day of the first calendar month following the month in which the election is made. We have reflected this provision in § 422.68(c).

Under section 1851(f)(4), an election that occurs as the result of a special election period is effective, to the extent practicable, in a manner determined by HCFA to promote continuity of coverage. We have reflected this provision in § 422.68(d).

At § 422.68(e) we are stating that an election of original Medicare made during a special election period by an individual age 65 as provided at § 422.62(c) is effective the first day of the first calendar month following the month in which the election is made.

10. Disenrollment by the M+C Organization (§ 422.74)

Section 1851(g)(3) specifies that M+C organizations may only disenroll individuals from an M+C plan for the following reasons: the individual fails to pay any basic and supplemental premiums on a timely basis; the individual engages in disruptive behavior; or the M+C organization terminates its coverage of all M+C eligible individuals in the area in which the individual resides.

In § 422.74, we have set forth the conditions under which M+C organizations can disenroll individuals. Section 1851(g)(3)(A) provides that, except as provided in section 1851(g)(3)(B), ''a Medicare+Choice organization *may not for any reason terminate*'' an individual's enrollment in ''a Medicare+Choice plan it offers.'' [Emphasis added.] We have included the three grounds for termination set forth in section 1851(g)(3)(B) in § 422.74. With respect to the ground in section 1851(g)(3)(B)(ii), under which an enrollee can be disenrolled for ''disruptive behavior'' as specified in standards established in regulations, we have implemented this ground for termination in two separate provisions. First, under § 422.74(b)(1)(ii), we refer to an individual who meets general standards for disruptiveness set forth in § 422.74(d)(2). Section 422.74(d)(2) refers to behavior of an individual that is ''disruptive, unruly, abusive, or uncooperative to the extent that his or her continued enrollment * * * seriously impairs the M+C organization's ability to furnish services. * * *'' We also separately refer to a different kind of ''disruption'' or failure to ''cooperate''; namely, fraud or abuse of the enrollee's enrollment card. This ground for termination is also based on section 1851(g)(3)(B)(ii), and standards for disenrollment on this basis are also included in § 422.74(d), in a separate paragraph (3).

In addition to implementing the grounds in section 1851(g)(3)(B), we also provide in § 422.74 for the termination of individuals who are no longer eligible for enrollment in the M+C plan, because they have left the area, lost entitlement to Medicare, or died. We believe that the prohibition in section 1851(g)(3)(A) on terminating an enrollee on grounds other than those set forth in paragraph (B) applies only to individuals who are otherwise *eligible* for enrollment in the plan. Clearly, if an individual does not meet the threshold requirements for eligibility, disenrollment is not only permissible but required.

We have established specific guidelines in § 422.74(d)(1) that the M+C organization must follow when disenrollment is based on failure to pay basic and supplemental premiums, including the requirement to send a notice of nonpayment within 20 days after the date that delinquent charges

are due. The notice must alert the individual that he or she is delinquent on a premium payment, provide the individual with an explanation of the disenrollment procedures and any lock-in provisions of the plan, and advise the individual that failure to pay the premiums within the 90-day grace period will result in termination of M+C coverage.

Note that in the section 1876 program, disenrollment for non-payment of premiums is treated differently. At § 417.460(c)(2), if a beneficiary pays the basic premium and other charges, but fails to pay the premium for optional supplemental benefits, the organization can discontinue the optional benefits, but cannot disenroll the beneficiary. However, under section 1851(g)(3)(B)(i), an M+C organization may terminate an election of a plan if any M+C monthly basic and supplemental beneficiary premiums are not paid on a timely basis.

We have retained the current processes described in § 417.460 for disenrollment for disruptive behavior and fraud and abuse. In the case of disenrollment for disruptive behavior, the M+C organization must ascertain that the individual's behavior is not related to the use of medical services or to diminished mental capacity. If an individual is disenrolled for disruptive behavior, HCFA will review the documentation submitted by the M+C organization and the beneficiary to determine whether the disenrollment requirements have been met.

We have included a qualifier for disenrollment when the individual no longer resides in the M+C plan's service area to conform to section 1851(b)(1)(B), which permits plans to offer a continuation of enrollment feature if the individual moves out of the service area. We have modified the existing regulatory text at § 417.460(h) which requires disenrollment when the individual loses entitlement to Part B benefits, to require disenrollment when an individual loses entitlement to Part A or Part B benefits. We have also addressed the process for disenrollment for plan termination or area reduction.

For all disenrollment situations, except those due to the death of the individual or loss of Part A or Part B benefits, we require M+C organizations to provide the individual with a written notice of the disenrollment that includes an explanation of why the M+C organization is planning to disenroll the individual and a description of the individual's right to a hearing under the M+C organization's grievance procedures.

The statute provides at section 1851(g)(3)(C) that individuals who are disenrolled from an M+C plan due to disruptive behavior or failure to pay basic or supplementary premiums will be deemed to have elected original Medicare. We have treated fraud and abuse by the enrollee in the same manner as other forms of disruptive behavior, with the individual being disenrolled into the original Medicare program. We believe that the result should be comparable because, in both cases, the individual's disruptive behavior has given the organization cause for the disenrollment. Individuals who lose entitlement to Part A or Part B benefits default to original Medicare because they no longer meet the requirements to receive Medicare benefits through an M+C plan, which requires entitlement to Part A and enrollment in Part B.

As previously discussed, special election periods are available to individuals who are disenrolled (or who disenroll) because of plan termination or service area or continuation area reduction or because they no longer reside in the M+C plan's service area or continuation area. Section 1851(g)(3)(C)(ii), however, stipulates that individuals who are disenrolled and who do not make an election during the special election period are deemed to have elected original Medicare.

11. Approval of Marketing Materials and Application Forms (§ 422.80)

Section 1851(h) contains requirements related to marketing by M+C organizations. These provisions are implemented in § 422.80. Section 422.80(a) implements the requirement in section 1851(h)(1) that all marketing material and application forms be submitted to HCFA for approval 45 days before distribution, and that such materials may only be used if HCFA does not disapprove such use by the end of this 45 day period. In section 422.80(b), we define ''marketing materials'' which must be submitted for approval under § 422.80(a).

Section 1851(h)(2) requires that M+C standards under section 1856 include guidelines for review of marketing materials under section 1851(h)(1) and § 422.80(a). Section 422.80(c) contains guidelines for HCFA's review of marketing materials under § 422.80(a). As provided for in section 1852(b)(2), these guidelines include existing marketing guidelines for HMOs and CMPs in § 417.428, which have been in effect since the inception of the existing Medicare risk contracting program.

Section 1851(h)(3) provides that, if HCFA has not disapproved the distribution of marketing materials or forms with respect to an M+C plan in an area, HCFA is deemed not to have disapproved the distribution in all other areas covered by the M+C plan and organization except with regard to any portion of the material or form that is specific to the particular area. This ''deemed approval,'' or ''1 stop-shopping,'' provision is included in the statute to address the needs of M+C organizations that operate in multiple states and within multiple HCFA Regional Office (RO) regulatory districts. Under the section 1876 program, a marketing piece submitted for HCFA review in multiple ROs was often susceptible to different regulatory interpretations by different RO staff; this occurrence could result in approval by one RO and a request for revisions by another RO. This phenomenon was primarily the result of RO staffs working within the environment of either an ''emerging'' market area or a ''mature'' area. The speed of review and approval of marketing materials should be enhanced by implementation of this statutory requirement.

Section 1851(h)(4) provides that M+C organizations shall conform to ''fair marketing standards'' included in the ''standards under section 1856,'' and requires that these standards prohibit an organization from providing cash or other monetery inducements for enrollment. Standards under section 1854(h)(4) are set forth in § 422.80(e). Again, as provided in section 1856(b)(2), these standards include existing section 1876 standards.

Section 1851(h)(4)(B) indicates that the fair marketing standards ''may include a prohibition against an M+C organization (or agent of such an organization) completing any portion of any election form used to carry out elections under this section on behalf of any individual.'' However, we have decided at this time not to prohibit an M+C organization (or agent of such an organization) from assisting beneficiaries in completing the election form. We recognize and understand that we must provide accommodations for persons with disabilities and for situations in which such a prohibition could represent a potential physical burden to beneficiaries. However, in general, we believe that it is good practice that the M+C eligible individual should complete and sign the election form. Currently, we have no way to check for any plan impropriety, especially in situations where beneficiaries require help in completing the enrollment form, except beneficiary allegations and requests for disenrollment. While we cannot

quantify the amount of inappropriate behavior, we know that some plans have completed election forms for beneficiaries fraudulently or have convinced beneficiaries to sign forms without explaining to them the contents and telling them the form is for enrollment (U.S. General Accounting Office report: ''HCFA Should Release Data To Aid Consumers, Prompt Better HMO Performance'', HS–97–23, October 1996.) Therefore, we request public comment on this issue and will provide further guidance in the final rule.

In the interim, we are providing at § 422.60(c) that persons who assist beneficiaries in completing forms should sign the form and indicate their relationship to the beneficiary. In addition, we encourage M+C organizations to use neutral parties such as family members, ombudsmen or counseling programs for those individuals who require assistance in completing forms.

Finally, in § 422.80(f), we specify that HCFA may permit M+C organizations to develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the M+C organization, and to furnish these materials only to such group members. While such materials must be submitted for approval under paragraph (a), HCFA will only review portions of these materials that relate to M+C plan benefits.

12. Medigap

Prior to the enactment of the BBA, Federal law provided only one opportunity for a Medicare beneficiary to purchase a Medicare supplement (Medigap) policy on a ''guaranteed issue'' basis. (Generally this means that the insurance company cannot deny the application, or charge extra, based on the individual's health experience.) This opportunity was during the 6-month period beginning with the date a beneficiary is both age 65 or over, and enrolled in Medicare Part B. Amendments made by the BBA now specify additional situations in which beneficiaries will, after July 1, 1998, be guaranteed access to certain types of Medigap policies on a guaranteed issue basis *if* they apply within 63 days after losing other coverage, and submit evidence of the date the prior coverage terminated. The law also requires the entity that provided the prior coverage to notify beneficiaries of these rights.

Therefore, while this regulation does not implement the Medigap provisions of the BBA, it is important to be aware of the implications for M+C organizations, since some of the situations covered by the Medigap provisions involve beneficiaries who leave M+C plans and return to original Medicare. The situations that will give rise to the obligation to notify the beneficiary will include, for example, termination of coverage by an M+C plan, or loss of coverage under an M+C plan due to a change in the individual's place of residence. The beneficiary also will have the right to guaranteed issue of a Medigap policy if he or she either enrolls in an M+C plan upon first becoming eligible for Medicare at age 65, or enrolls after previously being covered under a Medigap policy, and later disenrolls from the M+C plan within 12 months of the effective date of the M+C enrollment.

Because the Medigap provisions establish specific time deadlines for beneficiaries who wish to take advantage of these new rights, prompt action by M+C organizations to notify beneficiaries of their rights, and by HCFA to provide accurate evidence of recently terminated coverage, will be essential. CFA is committed to providing beneficiaries whose M+C coverage terminates under the specified circumstances with timely and accurate evidence of the recently terminated coverage. There are a number of ways in which we are considering providing the necessary evidence, including enabling Medigap insurers to query HCFA systems, if privacy and security issues can be resolved. HCFA is seeking comments on the most effective way to coordinate with Medigap insurers in order to protect beneficiaries' rights under the statute, and promote continuity of care.

We also urge M+C organizations to keep in mind that they will be obligated to notify beneficiaries whose coverage terminates of their rights under the Medigap provisions. Those provisions are complex—only certain beneficiaries will be entitled to guaranteed issue of Medigap policies, and their choice of policies will depend on the precise reason for termination of their coverage under the M+C plan. Further guidance is available from the National Association of Insurance Commissioners (NAIC), which on April 29, 1998 issued a revised Model regulation that incorporated the Medigap changes made by the BBA.

C. Benefits and Beneficiary Protections

1. General Requirements (§ 422.100)

Subpart C of these regulations details the scope of benefits a Medicare beneficiary is entitled to receive when electing coverage through an M+C plan. The statutory authority for most of the provisions of subpart C is found in section 1852, which outlines benefit requirements and provides authority for beneficiary protections under Medicare Part C. Many of the statutory provisions are the same as, or similar to, benefit provisions of section 1876. Therefore, much of the regulatory language of part 417 is retained for purposes of establishing M+C standards, as provided for in section 1856(b)(2) (which directs that the M+C standards be based on the analogous standards established under section 1876).

A principal difference between section 1876 provisions and the newly enacted law is that the new law permits a wider range of types of entities to assume risk for the coverage of benefits for Medicare enrollees. Section 1876 limited the Medicare contract option to organizations that operated as entities accepting full-risk, prepaid capitation for the provision of a comprehensive range of services and defined ''eligible organizations'' as a Federally qualified HMO (under title XIII of the Public Health Service Act) or a competitive medical plan (CMP). Except in a very few instances where waivers were granted during years when such waivers were authorized, the organizations had to offer such a product in the commercial marketplace in order to have a Medicare contract. From the point of view of benefit requirements imposed on plans, the new types of network plans are subject to the same benefit requirements applicable to organizations that would have met the definition of ''eligible organization'' under section 1876 (HMOs and CMPs). The requirements under the new law for network plans are in many cases identical to the requirements under section 1876.

While adding PPOs, indemnity insurers, and provider-sponsored organizations to the range of entities eligible for Medicare contracts, the BBA also permits non-network plans, such as private fee-for-service plans and M+C non-network MSA plans, to assume prepaid, capitated risk for services used by enrollees of these organizations. Medicare beneficiaries who elect these plans are not subject to the same constraints in use of providers that exist in network plans. Therefore, the benefit requirements applicable to these plans, and cost-sharing requirements, may be very different from those that apply to network plans. This section of the preamble mainly discusses the requirements for network plans. Sections III and IV of the preamble provide more extensive information about benefit requirements applicable to non-network M+C MSA plans and to

private fee-for-service plans, respectively.

All M+C organizations are required to cover the full range of Medicare benefits that enrollees would otherwise have been able to receive under original Medicare, subject to certain rules regarding available networks of providers. M+C organizations are further required to cover Medicare preventive benefits with the same frequency that they are covered under original Medicare (e.g., annual screening mammography examinations). Beneficiaries may be required to contribute to the cost of covered services in the form of cost-sharing provided for under the M+C plan. Beneficiaries may have to cover all costs until a deductible is met (including the high deductible provided for under an MSA plan (see section III of this preamble)), a percentage of costs in the form of coinsurance, or a fixed amount for services, in the form of a copayment. As discussed in subpart G below, there are limits that apply to the cost-sharing that can be imposed on beneficiaries under M+C plans. For benefits that are covered under original Medicare, the benefits must be obtained through providers meeting the conditions of participation of the Medicare program.

Organizations with network plans, which include coordinated care plans and network M+C MSA plans, are required to provide these services directly or through arrangements (i.e., written agreements with providers) in order to meet the availability and accessibility requirements of section 1852(d)(1) and § 422.112, discussed below.

In some situations, an M+C organization, for its network plan or plans, may be required to assume liability for services provided to Medicare enrollees through noncontracting providers. Under § 422.100(b), the organization is required to assume financial responsibility for the following items and services obtained from a provider that does not contract with the M+C organization:

- Emergency services as defined in § 422.2;
- Urgently needed services as defined in § 422.2;
- Renal dialysis services provided while the enrollee was temporarily outside the M+C plan's service area;
- Post-stabilization care as described in § 422.100(b)(iv); and
- For both network and non-network plans, services denied by the M+C organization and found upon appeal (under subpart M of this part) to be services the enrollee was entitled to have furnished or paid for by the M+C organization.

The requirements that the M+C organization assume financial liability for renal dialysis services, and post-stabilization care are new requirements introduced by the BBA that were not included in section 1876 requirements. The BBA also revised the definition of emergency services, as discussed elsewhere in the preamble.

''Post-stabilization care'' (also referred to in the Act as ''maintenance care'') means medically necessary, non-emergency services needed to ensure that the enrollee remains stabilized from the time that the treating hospital requests authorization from the M+C organization until—

- The enrollee is discharged;
- A plan physician arrives and assumes responsibility for the enrollee's care; or
- The treating physician and plan agree to another arrangement.

Section 422.100(b)(1)(iv) provides that an M+C organization is responsible for the cost of post-stabilization care provided outside the plan if they were pre-approved, if they were not pre-approved because the organization did not respond to the request by the provider of post-stabilization care services for pre-approval within 1 hour after the organization was asked to approve post-stabilization care, or if the M+C organization could not be contacted for pre-approval. M+C organization liability will extend until the organization has contacted the hospital to arrange for discharge or transfer. These requirements reflect comments we received on post-stabilization care in response to the **Federal Register** notice of January 20, 1998. The majority of commenters advocated that we establish a timeframe for an M+C organization's response to a request for approval. Because we agree that an untimely response to a request for approval would unduly delay the delivery of the post-stabilization care services, thereby compromising their effectiveness, we have established a 1-hour timeframe in the regulation as an enrollee protection. Because a completely accurate assessment of an enrollee's need for post-stabilization care services cannot be made until the enrollee is stabilized, we expect that the provider of the post-stabilization care services will not request the M+C organization's approval of the services until after the enrollee is stabilized, at which time enough details about the enrollee's condition should be known to allow the organization to make an informed decision on whether to approve the care almost immediately. We welcome comments on this issue.

In the case of payments to noncontracting providers for covered items and services, the M+C organization's obligation is met when it provides for payment in an amount the provider would have received under original Medicare (including payment from the organization and beneficiary cost-sharing under the plan).

The benefits offered by an M+C plan may be divided into two major components, ''basic benefits'' and ''supplemental benefits.'' Basic benefits in an M+C plan include all Medicare-covered services (except hospice) and additional benefits. Basic benefits are discussed below, and special rules for M+C enrollees electing hospice are set forth in § 422.266 and discussed in section II.F.9. of this preamble. Supplemental benefits include both mandatory and optional supplements, which we also discuss below.

Section 1852(a)(1) stipulates that M+C organizations offering an M+C plan (or plans) must offer it to all Medicare beneficiaries eligible to elect the plan who reside in the service area of the M+C plan at a uniform premium with uniform cost sharing. An organization may offer more than one plan in the same service area. The premium and cost-sharing may vary among plans within the same organization. We will review each M+C plan offered by the same organization to ensure that it is not designed to promote discrimination, discourage enrollment, steer specific subsets of Medicare beneficiaries to particular M+C plans, or inhibit access to services.

2. Requirements Relating to Basic Benefits (§ 422.101)

With the exception of special rules concerning hospice care and M+C coverage that begins during an inpatient hospital stay (described in §§ 422.266 and 422.264, respectively), a Medicare enrollee is entitled to have the M+C organization provide all Medicare-covered services that are available in the geographic area in which services are covered under the plan.

M+C organizations are required to provide their enrollees with services covered under original Medicare and available to beneficiaries residing in the geographic area in which services are covered under the plan, as we provide at § 422.101(a). Organizations must also abide by our national coverage decisions, as well as specific written policies of the Medicare carrier or intermediary with jurisdiction for claims (if the encounter had occurred under original Medicare) in the

geographic area served by the plan. (These policies are sometimes called ''local medical review determinations.'') In cases where services are covered under the plan in an area that includes jurisdictions of more than one contractor for original Medicare, and the contractors have different medical review policies, the plan must apply the medical review policies of the contractor in the area where the beneficiary lives.

In addition, the organization is required to provide ''additional benefits,'' which include health care services not covered by Medicare, as well as reductions in premiums or cost sharing for covered services. As discussed in section II.A of this preamble, we use the term ''basic benefits'' to encompass all Medicare-covered benefits (except hospice services) and additional benefits. These benefits are determined by our approval of an M+C organization's Adjusted Community Rate (ACR) proposal for a given M+C plan and must be provided uniformly to all Medicare enrollees electing that plan. Additional benefits are generated when the average payment rate for a plan exceeds the adjusted community rate, thereby producing a surplus known as the ''excess amount.'' (See section II.F of this preamble for a more thorough discussion of the requirements that apply to additional benefits, which are set forth under § 422.312.)

In the case of an M+C private fee-for-service plan or a non-network M+C MSA plan, the obligation to cover Medicare services is not limited to services available in the plan's approved service area. Rather, in this context, we interpret ''geographic area served by the plan'' in section section 1852(a)(1)(A) to mean the area within which the M+C private fee-for-service or non-network M+C MSA plan enrollee has the right to receive covered services under the plan.

Under our authority in section 1856(b)(1) to establish standards under the M+C program, § 422.100(h) establishes special rules for influenza vaccine, pneumococcal vaccine, and screening mammography. Section 422.100(h)(2) prohibits enrollee cost-sharing for influenza vaccine and pneumococcal vaccine. Under original Medicare, there is no cost-sharing imposed on these items, and we believe congressional intent is for Medicare beneficiaries to have maximum possible access to both vaccines. We note that original Medicare provides for beneficiary payment of coinsurance for mammography screening; therefore, a plan may also impose copayment or coinsurance for this service.

Also note that beneficiaries under original Medicare may ''self-refer'' and directly access screening mammography and influenza vaccine. We have established a similar standard in § 422.100(h)(1) for M+C enrollees.

3. Supplemental Benefits (§ 422.102)

Section 1852(a)(3) provides for supplemental benefits. These benefits are health care items and services beyond the basic benefits described above and are categorized as either mandatory or optional.

Mandatory supplemental benefits are benefits not included in basic benefits which must be purchased by all beneficiaries who enroll in the M+C plan under which they are included. Mandatory supplemental benefits may be offered under coordinated care plans and fee-for-service plans only, and must be approved by HCFA. HCFA will approve such benefits unless we determine that they would substantially discourage enrollment in the plan. Specifically, we will determine whether the inclusion of the mandatory supplemental benefits would discourage particular subcategories of Medicare beneficiaries from enrolling (e.g., those residing in certain parts of a plan service area). These benefits are addressed in § 422.102(a).

Section 1852(a)(3)(C) provides that nothing in paragraph (3) of section 1852(a), addressing supplemental benefits, shall be construed to prevent a fee-for-service plan from offering supplemental benefits covering the balance billing permitted under section 1852(k)(2)(A)(i) and § 422.216(b)(1) and additional services. See discussion of M+C private fee-for-service plans in section IV of this preamble. The only provision in section 1852(a)(3) that could possibly be construed to prevent a private fee-for-service plan from offering such benefits would be the right of the Secretary, and of HCFA under these regulations, to disapprove mandatory supplemental benefits. We accordingly wish to make it clear that HCFA will not disapprove such benefits in the case of a private fee-for-service plan. (As discussed below in subpart G, HCFA does not have the right to review or approve the amount that a private fee-for-service plan charges for supplemental benefits.) We believe that the foregoing statement is sufficient to give effect to section 1852(a)(3)(C).

Optional supplemental benefits are benefits beyond basic benefits that may be purchased by an M+C plan enrollee at his or her option. If a plan offer optional supplemental benefits, it must offer those benefits to all enrollees in the M+C plan. While optional supplemental benefits may be offered under all types of plans, in the case of MSA plans, there are limits, discussed in section III of the preamble, on the nature of optional supplemental benefits that can be offered.

Under mandatory supplemental benefits for coordinated care plans, an M+C organization may require an enrollee who elects an M+C plan to accept and pay for items and services beyond basic benefits if he or she wants to enroll in a particular M+C plan. If an organization requires supplemental benefits, it must do so uniformly for all Medicare beneficiaries enrolled in that plan. As provided for at section 1852(a)(3)(A), we will approve such offerings unless we determine that would substantially discourage enrollment in the plan. We will determine whether the mandatory supplemental benefits would discourage subcategories of Medicare beneficiaries from enrolling (e.g., those residing in certain parts of a plan's service area).

An organization may also offer optional supplemental benefits within an M+C plan. In this case, the beneficiary is free to choose to accept or decline the supplement. In the case of both mandatory and optional supplemental benefits, the benefits are paid for by (or on behalf of) the individual electing the M+C plan.

Sections 422.103 and 422.104, addressing benefits under MSA plans generally, and optional supplemental benefits under an MSA plan, are discussed in section III. below.

4. Special Rules for Point-of-Service (POS) Option (§ 422.105)

This section of the rule codifies our existing policy for point-of-service plans. Because these policies have not previously appeared in regulations, we welcome comments.

A POS benefit is an option that an M+C organization may offer through an M+C coordinated care plan or network M+C MSA plan to provide Medicare enrollees with additional choice in obtaining specified health care items and services from entities that do not have a contract with the M+C organization. A coordinated care plan may offer a POS option as an additional benefit, a mandatory supplemental benefit, or an optional supplemental benefit. A network MSA plan may only offer a POS option as a supplemental benefit.

Under POS, the health plan generally provides partial reimbursement to enrollees for items and services obtained from non-network providers. The enrollee may be required to pay a premium for the benefit unless the

benefit is offered as an additional benefit. The Act contains two mentions of the term ''point of service'' as it relates to M+C plans. Section 1851(a)(1)(A) states that an HMO may include a POS option, and section 1852(c)(1)(C), requires disclosure to enrollees of ''any point-of-service option (including the supplemental premium for such option).'' Therefore, the Act indicates that HMOs could offer POS products, and that there could be a supplemental enrollee premium for such a product.

We currently permit HMOs and CMPs to offer POS products. There is no specific statutory reference to such a product in section 1876; the statutory basis for allowing Medicare HMOs to provide POS products lies in the additional and supplemental benefit offerings an HMO may have under section 1876. We believe that under the structure of the M+C program, any coordinated care plan or network M+C MSA plan may offer a POS product.

The regulations at § 422.105 governing the POS benefit are largely a restatement of our previously issued guidelines. In issuing the guidelines, we were particularly concerned with assuring the continued accessibility and availability of medically necessary care within the Medicare plan's approved network. We also emphasized that organizations are responsible for: members' continuity of care; ensuring beneficiaries are fully informed about how the POS benefit would be implemented; and the potential financial liability of the individual. We also required organizations to provide data to us about the POS benefit, including expenditures and levels of POS utilization, and the effect on the financial status of the organization. Moreover, the guidelines required the plans to maintain a record-keeping system to make information on utilization of the POS benefit available to plan providers. These previous operational policy requirements are carried over into § 422.105.

There are some changes in § 422.105 to the guidelines we issued under section 1876, however. One has to do with POS coverage available for in-network items and services. Under the guidelines, we permitted HMOs and CMPs to include network providers who could be paid through the POS option. These regulations eliminate that option. Additionally, under § 422.105, we will now require plans to place a cap on a beneficiary's total annual financial liability under a POS benefit. In another change, we are eliminating separate solvency standards for POS products. Each of these changes is discussed below.

Although HCFA guidelines did permit a Medicare beneficiary to use a POS option to seek, for example, ''direct access'' to a specialist within the plan's network, and thereby avoid any prior authorization requirement or other plan rules relating to access to particular providers, we believe such a feature of a POS option is inconsistent with the concept of a network plan and not a desirable feature of a POS option. The basic access and availability requirements both of sections 1876 and 1852(d) require that benefits be made available, through providers selected by the M+C organization, in a manner that ensures availability, accessibility and continuity of care. If the care an individual seeks from a network provider is necessary care, the individual should be able to obtain that care through the network, following network rules. Although the enrollee might not receive treatment from the particular provider he or she prefers, the organization and its contractors are obligated to make covered services available to all enrollees through network providers. We do not believe it is appropriate to use the POS benefit to circumvent network rules.

In § 422.105 we also specify that an M+C organization offering a POS benefit establish an annual limit on a beneficiary's maximum financial liability when using a POS benefit. We require a financial limit to alert beneficiaries to their maximum potential financial liability in using their POS benefit. We consider it a critical part of beneficiary information that enrollees are clearly informed about all of their potential costs when enrolling in an M+C plan.

Another change from existing policy in § 422.105 is the elimination of the additional solvency requirements that have been imposed under the POS guidelines (though reporting requirements relating to solvency remain). The Act gives the States primary responsibility for setting and enforcing solvency standards for M+C plans (other than a provider-sponsored organization with a waiver of the State licensure requirement), and our imposition of additional solvency requirements on POS products is inconsistent with the States' responsibility. (In fact, because of solvency concerns, many States require licensure as an indemnity insurer if an HMO wishes to offer a POS product.) We will continue to require M+C organizations to comply with this reporting requirement, as was the case with Medicare contractors under section 1876. This reporting requirement is not superseded by the Act's preemption provision relating to benefits in section 1856(b)(3)(B).

5. Special Arrangements With Employer Groups (§ 422.106)

An M+C organization may negotiate with an employer group to provide benefits to Medicare members of the employer group who are enrolled in an M+C plan offered by the organization and these benefits must be provided uniformly to members of the group. While these negotiated employer group benefits may be designed to complement benefits available to Medicare beneficiaries enrolled in the plan, they are offered by the employer group independently as the product of private negotiation. These benefits may include contributions on the employee group member's behalf toward M+C plan premiums or cost-sharing for which the Medicare eligible group member is responsible, or benefits not covered by the M+C plan, for which premiums and cost-sharing may be charged. We do not review such employer group benefits, premiums, or cost-sharing amounts.

6. Medicare Secondary Payer (MSP) Procedures (§ 422.108)

As specified in section 1852(a)(4), if a Medicare enrollee receives covered items and services from an M+C organization for which the enrollee is entitled to benefits under a State or Federal workers' compensation law or plan, any no-fault insurance, or any liability insurance policy or plan (including a self-insured plan), the M+C organization may charge the insurance carrier, employer or other entity that is responsible to pay for the provision of those items and services. The M+C organization may also charge the Medicare enrollee to the extent that the enrollee has been paid by the carrier, employer, or other entity for those items and services. In addition, an M+C organization may charge a group health plan or large group health plan for items and services for which Medicare is a secondary payor.

In this area, pursuant to section 1856(b) (1) and (2), we are retaining for M+C organizations the requirements that applied to HMOs and CMPs under part 417.

7. Effect of National Coverage Determinations (NCDs) (§ 422.109)

This provision implements section 1852(a)(5). Under this rule, M+C organizations are not required to assume risk for the costs of certain ''significant cost'' NCDs until an adjustment has

been made in the per capita rate to reflect the NCD. A national coverage determination is a national policy statement regarding the coverage status of a specified service that HCFA makes as a program memorandum or manual instruction. The term does not include coverage changes mandated by statute. Past NCDs have included items such as heart transplants.

On February 22, 1994 HCFA published a notice of proposed rule making (NPRM) to define ''significant cost'' and other requirements for NCDs as they applied to section 1876 risk contracting plans. With one exception discussed below, we are including in this rule the policies included in the February 22, 1994 proposed rule. For example, we have maintained the definition of ''significant cost'' as $100,000 for a single NCD service for calendar years 1998 and 1999. We are providing for an automatic adjustment of a single service threshold amount to reflect rising costs, and will adjust the dollar threshold by the national per capita growth percentage used to calculate the annual capitation rates to pay M+C organizations. We are also providing an alternative definition for lower cost services that will affect a large number of beneficiaries. For the cost of all of the services furnished nationwide as a result of a particular NCD, we have redefined significant cost as 0.1 percent of the national standardized annual capitation rate (which is used in calculating the annual capitation rates used to pay M+C organizations) multiplied by the total number of Medicare beneficiaries nationwide for the applicable calendar year.

This rule also describes how the NCD will be provided to M+C plan enrollees during the period the M+C organization is not at risk for the new or expanded benefit established by the NCD, including procedures to pay M+C organizations and the policies affecting beneficiary liability. It is in this area that this rule differs from the February 22, 1994 proposed rule. That proposed rule reflected the NCD provision that applied to HMOs with risk contracts under section 1876. There is one key difference between the NCD provision in section 1876 and the NCD provision under the new M+C. Like the new NCD provision in section 1852(a)(5), section 1876(c)(2)(B) provided that services required under certain mid-year NCDs were excluded from risk contracts until the first year in which payment for the services is reflected in capitation payments. However, under Section 1876(a)(6), original Medicare coverage of such NCD services was identified as an exception to the rule that only the risk-contracting HMO could receive Medicare payment on behalf of one of its enrollees. Therefore, an HMO enrollee was not required to receive NCD services excluded from the HMO's contract through the HMO, and could receive the services either from the HMO or from any other Medicare provider, and Medicare would pay. This was reflected in the February 2, 1994 proposed rule.

Under the M+C program, however, there is no similar exception for excluded NCD services providing that only an M+C organization may be paid by Medicare on behalf of an enrollee in an M+C plan offered by that organization. We believe that this difference reflects Congress' intent that beneficiaries be required to receive services through their M+C organization, under the same rules that apply to any other non-urgent and non-emergency services. Under the new NCD provision, only the method that HCFA pays the organization for the services, and the cost-sharing that applies to such services differs from other services. If the excluded NCD services are received from, or through, the M+C organization, the organization will be paid on a fee-for-service basis for those services. If the services are not available from the plan, the organization will pay the authorized provider after receiving fee-for-service from the intermediaries or carriers.

Pursuant to our authority under section 1856(b)(1), we are expressly requiring that the M+C organization provide the NCD services in question on a fee-for-service basis.

8. Discrimination Against Beneficiaries Prohibited (§ 422.110)

The current rule reflects section 1852(b), and the details provided in § 422.110 are consistent with existing policy and regulation. In general, M+C organizations may not discriminate among Medicare beneficiaries based on health-related factors with the exception that organizations may not enroll new beneficiaries with end-stage renal disease. For further discussion of discrimination provisions affecting M+C enrollees with ESRD, see the discussion in section II.B.1 of this preamble.

9. Disclosure Requirements (§ 422.111)

In section 1852(c), the Act lists several areas where an M+C organization must disclose specific information to each M+C plan enrollee. These requirements are, in large part, a codification of existing program administration requirements under section 1876, and we detail these requirements in § 422.111 of the regulations. In general, an M+C organization is required to provide in a clear, accurate, and standardized form information relating to: service area; benefits access; out-of-area coverage; emergency coverage; supplemental benefits; prior authorization rules; plan grievance and appeals procedures; disenrollment rights and responsibilities; and information about the M+C organization's quality assurance program.

M+C organizations are also required to provide further information on a beneficiary's request, which we also detail in § 422.111 of the regulation text. These ''upon request'' requirements include: general coverage and comparative plan information; information on utilization control procedures; information on grievances and appeals; information on the financial condition of the M+C organization; and a summary of physician compensation arrangements.

10. Access to Services (§ 422.112)

The requirements of section 1852(d) of the Act (concerning access to services) are being implemented through this rule, in part, by applying existing regulations and policies pursuant to our authority in section 1856(b)(1) to establish standards under the M+C program. We are also addressing recommendations from the President's ''Consumer Bill of Rights and Responsibilities'' (CBRR), and incorporating the ''Quality Improvement System for Managed Care'' (QISMC) standards.

For example, our existing policy shaped the language in § 422.112(a)(1)(i) requiring M+C organizations to maintain and monitor a network of appropriate providers, supported by written agreements sufficient to certify beneficiary access to covered services. The CBRR shaped the access to (and continuity of) specialist services text in § 422.112(a), as well as provisions for provider credentialing and timeliness of access, among other consumer protections. We also include a provision at § 422.112(a)(4)(vii)for M+C organizations to ensure ''cultural competency'' in the provision of health care. This provision reflects CBRR recommendations that M+C organizations make a particular effort to ensure that enrollees with limited English proficiency, limited education, or other socioeconomic disadvantages receive the health care to which they are entitled.

The Consumer's Bill of Rights and Responsibilities also recommends that women be able to choose a women's

health care specialist within network for the provision of routine and preventive women's health care services. In support of this recommendation, § 422.112(a)(1)(iii)(A) requires M+C network plans to provide direct access to a women's health specialist within the network for routine and preventive women's health care services provided as basic benefits, as defined in § 422.2. We note that coverage of routine and preventive health services under original Medicare is limited. For example, original Medicare covers a screening pap smear and a screening pelvic exam, including a clinical breast exam, once every 3 years under normal circumstances. M+C plans must cover routine and preventive health services with at least the same frequency as they are covered under original Medicare and may offer expanded services in these areas as additional benefits.

M+C plans satisfy the requirement in § 422.112(a)(1)(iii)(A) by providing direct access to gynecologists, certified nurse midwives, and other qualified health care providers for provision of routine and preventive women's health services. At the same time, M+C plans are required to provide women enrollees with continued access to their primary care physician to ensure continuity of care. We welcome comments on this issue.

In § 422.112(a)(1)(iii)(B), we require that plans have HCFA-approved procedures—

- To identify Medicare enrollees with complex or serious medical conditions;
- For assessment of those conditions, including medical procedures to diagnose and monitor them on an ongoing basis; and
- For establishment and implementation of a treatment plan appropriate to those conditions, with an adequate number of direct access visits to specialists to accommodate the treatment plan. To meet these requirements and those of § 422.112(a)(5)(v)(A), M+C plans must conduct a baseline and establish a treatment plan for people with complex or serious medical conditions. This assessment should be completed within timeframes deemed appropriate by M+C plans based on the needs of its enrollees, but, in general, should occur within 90 days of the effective date of enrollment.

Section 422.112(a)(5)(v)(A) also requires M+C plans to conduct a baseline health assessment for all new Medicare enrollees (i.e., not limited to those with complex or serious medical conditions) in a timely manner. We believe that this initial assessment should also be performed based on timelines deemed appropriate by the plan, but not later than 90 days after the effective date of enrollment. We welcome comments regarding timely baseline assessments both for new enrollees and those with complex or serious medical conditions.

Note that, as indicated in the heading of § 422.112(a), some access provisions apply only to network organizations, (i.e., coordinated care plans and network MSAs), while others (§ 422.112(b)) apply to all M+C organizations.

Section 422.112(b) states that M+C organizations must provide coverage of emergency services and urgently needed services even in the absence of the organization's prior approval and without regard to the provider's contractual relationship with the M+C organization. For definitions of emergency and urgently needed services, see § 422.2.

This section continues the prohibition at § 417.414(c)(1) on prior authorization requirements for emergency services as explicitly provided by 1852(d) and continues the § 417.414(c)(1) regulatory prohibition on prior authorization requirements for urgently-needed services. This section also establishes a prohibition on prior authorization requirements for emergency services provided within the plan because the prohibition on prior authorization at section 1852(d) applies to services provided both within and outside the organization.

Consistent with the new definition of ''emergency medical condition'' in section 1852(d)(3)(B), we are codifying longstanding *HMO/CMP Manual* policy (§ 2104) of prohibiting retrospective denial for services which appeared, to the prudent layperson, to be emergencies, but which turn out to be nonemergency in nature.

We are establishing that when a physician or other representative affiliated with the organization instructs the enrollee to seek emergency services within or outside the organization, the organization is responsible for payment for medically necessary emergency services provided to the enrollee.

We are codifying in regulation an *HMO/CMP Manual* policy (§ 2104) specifying that the decision of the examining physician treating the individual enrollee prevails regarding when the enrollee may be considered stabilized for discharge or transfer.

We are establishing limits on cost-sharing for emergency services obtained outside of the M+C plan's provider network equal to of the lesser of $50 or what the organization may charge for emergency services provided within the plan's provider network. We are imposing this requirement in order to facilitate and ensure access to covered emergency services provided other than through the organization. We do not view this requirement as overly burdensome. A review of 1997 data on what Medicare HMOs and CMPs charged for emergency services found that 93 percent of contracts charged $50 or less. We believe that it may be appropriate to lower this limit or eliminate cost-sharing altogether, and would welcome comments on this subject.

Note that an M+C organization's failure to provide medically necessary emergency services could result in intermediate sanctions for failing to provide coverage, or payment, or through actions (such as a prospective refusal of payment) that could result in discharge or transfer of an unstabilized patient. The new coverage requirements for M+C enrollees do not affect the rights of all persons (whether or not they are Medicare beneficiaries) to receive emergency services at any Medicare-participating hospital that offers emergency services (under the patient ''anti-dumping'' statute in section 1867).

11. Access to Services Under an M+C Private Fee-for-Service plan (§ 422.114)

In the case of an M+C organization that offers an M+C private fee-for-service plan, that organization must demonstrate that it has a sufficient number and range of providers willing to furnish items and services under the plan. An M+C organization meets this requirement if, with respect to a particular category of providers, the organization has:

- Payment rates that apply under original Medicare for the provider and service in question;
- Contracts or agreements with a sufficient number and range of providers to furnish the items and services covered under the M+C private fee-for-service plan; or
- A combination of the two.

Additionally, an M+C private fee-for-service plan must permit enrollees to obtain items and services from any entity that is authorized to provide items and services under Medicare Parts A and B and agrees to provide services under the terms of the M+C private fee-for-service plan. For a fuller discussion of M+C private fee-for-service plans, see section IV of this preamble.

12. Confidentiality and Accuracy of Enrollee Records (§ 422.118)

M+C organizations are required to safeguard the confidentiality and

accuracy of enrollee records that identify a particular enrollee, including both medical documents and enrollment information. An M+C organization may circulate this information within the organization to coordinate care for a Medicare enrollee. The M+C organization may not, however, circulate this information outside the organization without specific authorization from the Medicare enrollee. M+C organizations are prohibited from selling (or circulating outside the organization) names and addresses of enrollees for any purpose, including scientific study.

Additionally, the M+C organization must maintain records in an accurate and timely manner and ensure timely access to enrollees who wish to examine their records. Moreover, the M+C organization must abide by all Federal and State laws regarding confidentiality and disclosure for mental health records, medical records, other health information, and enrollee information.

13. Information on Advance Directives (§ 422.128)

Advance directives are documents signed by a patient that explain the patient's wishes concerning a given course of medical care should a situation arise where he or she is unable to make these wishes known. The M+C organization is responsible for documenting advance directives in a prominent part of the Medicare beneficiary's medical record. Accordingly, pursuant to our authority in section 1856(b)(1) and (2) to establish M+C standards, we are retaining for M+C organizations the requirements that applied to HMOs and CMPs under part 417.

14. Protection Against Liability and Loss of Benefits (§ 422.132)

Each M+C organization must adopt and maintain satisfactory arrangements to protect Medicare enrollees from incurring liability for payment of any fees that are the legal obligation of the M+C organization. By reference in § 417.407(f) (implementing regulations for section 1876), enrollee protections described in § 417.122 are unchanged by the BBA, and their application to M+C organizations are carried forward in this section.

Medicare law requires that Medicare contracting M+C organizations make Medicare covered services ''available and accessible.'' Section 1852(d)(1), in describing access to services, allows M+C organizations to select the providers from whom benefits may be obtained so long as ''the organization makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness * * *'' We believe these sections require health plans to provide the same accessibility afforded by HCFA to beneficiaries under original Medicare.

D. Quality Assurance

1. Overview

Subpart D of part 422 contains the quality assurance requirements for M+C organizations. These requirements implement and are based on the provisions of section 1852(e) of the Act. They also incorporate the requirements of section 1851(d)(4)(D), which provides that the information made available to Medicare beneficiaries for plan comparison purposes should include plan quality and performance indicators, to the extent available. Section 1852(e)(1) sets forth the general rule that each M+C organization must establish an ongoing quality assurance program, consistent with implementing regulations, for the health care services it provides to enrollees in the organization's M+C plans. The rest of section 1852(e) contains the required elements of the quality assurance program, requirements for external review, and provisions concerning the use of accreditation organizations to determine compliance with the quality assurance requirements.

The provisions of section 1852(e) represent a significant expansion in the scope of the statutory quality assurance provisions applicable to managed care organizations that contract with the Medicare program. Existing section 1876(c)(6) contains a general requirement similar to that of section 1852(e)(1) that an organization must have a quality assurance program, but it provides very limited guidance as to the nature of this program. The only required elements of a quality assurance program under section 1876(c)(6) are that it stress health outcomes and include physician review of the procedures used in the provision of health care services. Like section 1876(c)(6), existing quality assurance regulations (§ 417.418 and, by reference, § 417.106(a)) contain few detailed requirements concerning quality assurance. The regulations basically restate the statutory requirements relating to health outcomes and physician review and then add two broad requirements regarding data collection and the need for written procedures for taking remedial action.

In contrast, section 1852(e) sets forth a series of specific elements that now must be addressed in an M+C organization's quality assurance program. As discussed in detail below, these requirements focus on the need for an M+C organization, with respect to each M+C plan that it offers, to operate an outcome-oriented quality assessment and performance improvement program that achieves demonstrable improvements, across a broad spectrum of care and services, in the health, functional status, and satisfaction of its enrollees. (Note that some of the specific performance improvement requirements of the statute do not apply to M+C non-network MSA plans or PFFS plans, as addressed under § 422.152(e).) The collection, evaluation, and reporting of the data necessary to demonstrate quality improvements are also critical elements of each M+C organization's quality-related responsibilities.

2. Origins of the Quality Assessment and Improvement Requirements

The regulations to implement sections 1852(e)(1) and (2) and section 1851(d)(4)(D) incorporate each of the explicit statutory requirements into new subpart D. Consistent with our explicit statutory authority under section 1851(e), these regulations include additional detail to clarify how an M+C organization can meet the statutory requirements. Like Congress, we recognize that the state of the art in quality assurance has evolved from a problem-focused approach, with an emphasis on remedial action, to a proactive approach aimed at achieving continuous, systemic quality improvement. In recent years, HCFA, the States, and other managed care purchasers have been involved in a series of initiatives aimed at improving the quality of care and services provided to managed care enrollees. Examples of such efforts include:

- The Quality Assurance Reform Initiative (QARI), which developed and tested standards for States to use in monitoring and improving quality in Medicaid contractors, with a particular emphasis on plans' own internal quality improvement efforts.
- Uniform data collection and reporting instruments, such as the Health Plan Employer Data and Information Set (HEDIS 3.0), which was developed by the National Committee for Quality Assurance (NCQA). Use of HEDIS 3.0 is now a contract requirement for Medicare risk-based managed care plans, under section 1876 and is intended to allow assessment and comparison of plan performance.
- Projects to enhance the role of Medicare Peer Review Organizations (PROs) in evaluating and improving managed care plan quality, including

the development and testing of a minimum set of performance evaluation measures and quality improvement projects developed through collaboration between PROs and managed care organizations. States have undertaken similar efforts through Medicaid External Quality Review Organizations (EQROs).

Among the most comprehensive of recent quality-related initiatives is the Quality Improvement System for Managed Care (QISMC). During the past 2 years, HCFA has been working closely with other Federal and State officials, as well as representatives of beneficiary advocacy groups and the managed care industry, to develop quality standards that can better ensure that managed care organizations that contract with HCFA protect and improve the health and satisfaction of their enrollees. QISMC is the product of these efforts. Originally drafted based on the authority of section 1876, it builds on a variety of recent HCFA and State efforts, like those mentioned above, to promote the assessment and improvement of managed care quality. The QISMC standards are in the final stages of development at this time and are being modified to reflect the quality-related requirements under the BBA. Once QISMC is complete, we believe it will offer a uniform set of quality standards that can be used by HCFA and the State Medicaid agencies to determine whether a managed care organization can meet the quality assurance requirements necessary to become and remain eligible to enter into a Medicare or Medicaid contract.

The QISMC initiative is substantially in accord with the quality assurance requirements of new section 1851(e). For example, both the statutory requirements and the QISMC quality standards emphasize measurement of health outcomes, consumer satisfaction, the accountability of managed care organizations for achieving ongoing quality improvement, the need for intervention to achieve this improvement, and the importance of data collection, analysis, and reporting. Moreover, as noted above, representatives of all segments of the managed care community have contributed to the development of QISMC, and generally support HCFA's intention to eventually require managed care organizations to meet the QISMC standards. Given the shared goals of the BBA and QISMC standards, and HCFA's implementation plans for QISMC, we believe it is appropriate to establish new M+C quality assurance regulations that reflect those QISMC standards that mirror the intent of the statute.

Although we have not included in the regulations the level of detail embodied in QISMC, we have attempted to build into the regulations some principles from QISMC that can guide M+C organizations in meeting the quality requirements established by the statute. For example, § 422.152(d) establishes objective standards concerning the improvement projects that are required of M+C organizations, in accordance with the statutory requirements concerning an organization's responsibility to take action to improve quality (such as section 1852(e)(2)(A)(xi) of the Act.

Although QISMC remains an evolving document, several of the discussions below of the ways in which organizations can meet the M+C quality requirements are informed to some degree by the underlying details contained in QISMC. Also, as discussed below, we anticipate that requirements pertaining to a plan's quality assessment and performance improvement responsibilities may be implemented as part of the M+C contracting process. QISMC standards may be a guide in implementing the requirements in the BBA and these regulations. Eventually, we believe QISMC can serve to define what HCFA's expectations are with regard to an M+C organization's quality assessment and improvement responsibilities. (A copy of the most recent version of QISMC is available at HCFA's website, www.hcfa.gov/quality/qlty-3e.htm.)

3. Quality Assessment and Performance Improvement Requirements (§ 422.152)

This section of the regulation implements paragraphs (e)(1) and (2) of section 1852. Subject to certain exceptions for M+C PFFS and non-network MSA plans, which are discussed below, the statute requires that an organization's quality assurance program meet the following requirements with respect to each plan that it offers:

(i) Stress health outcomes and provide for the collection, analysis, and reporting of data (in accordance with a quality measurement system that HCFA recognizes) that will permit measurement of outcomes and other quality indices.

(ii) Monitor and evaluate high-volume and high-risk services and the care of acute and chronic conditions.

(iii) Evaluate the continuity and coordination of the care that enrollees receive.

(iv) Be evaluated on an ongoing basis as to its effectiveness.

(v) Include measures of consumer satisfaction.

(vi) Provide HCFA access to the information it needs to monitor and ensure the quality of the care provided.

(vii) Provide for physicians and other health care professionals to review the process followed in providing health care services.

(viii) Establish written protocols for utilization review, based on current standards of medical practice.

(ix) Have mechanisms to detect both underutilization and over utilization of services.

(x) Establish or alter practice parameters when areas needing improvement are identified.

(xi) Take action to improve quality and assess the effectiveness of that action through systematic follow-up.

(xii) Make available to HCFA information on quality and outcomes measures to facilitate beneficiary comparisons and choice of health care options (in such form and on such quality and outcomes measures as HCFA determines is appropriate).

As noted above, section 1852(e)(1) also requires that the organization's quality assurance program be consistent with any regulation developed by HCFA. Therefore, § 422.152 reflects the statutory requirements listed above, as well as those implementing requirements that are consistent with, and necessary to accomplish, the intent of the Act. While certain requirements in section 1852(e)(2) that expressly refer to ''improvement'' in quality do not apply to all types of M+C plans, we believe that all of the requirements in section 1852(e) are geared toward improving quality, not simply monitoring it. For this reason, we are using the term ''quality assessment and performance improvement program'' to refer to the program that is required of all M+C plans, which section 1852(e)(1) refers to as a ''quality assurance program.'' We accordingly use the term ''quality assessment and performance improvement program'' in the heading of § 422.152 and in the general rule at § 422.152(a).

a. Requirements for M+C Coordinated Care Plans and Network MSA Plans. Sections 422.152(b) through (d) set forth requirements that M+C organizations must meet with respect to M+C coordinated care plans and network MSA plans. As alluded to above, as directed by section 1852(e), these requirements reflect a departure from the problem-focused approach to ensuring quality that was prevalent in the past. Thus, under these regulations, it will no longer be sufficient for organizations to identify and correct problems in their operations—they must now focus on systemic quality

improvement as well. This approach is also consistent with HCFA's responsibility to demand value in the form of positive outcomes from the organizations with which we contract.

To implement this approach, § 422.152(b) establishes two basic quality assessment and performance improvement requirements: (1) measurement and reporting of performance; and (2) conducting performance improvement projects that achieve, through ongoing measurement and intervention, demonstrable and sustained improvement in significant aspects of both clinical care and nonclinical care areas that can be expected to affect health outcomes and member satisfaction. The specific requirements associated with the measurement and reporting of performance and the execution of performance improvement projects are set forth under § 422.152(c) and (d), as discussed in detail below. Before turning to that discussion, however, we note that § 422.152 also incorporates statutory requirements from section 1852(e)(2)(viii), (ix), and (xii), as listed above, concerning written utilization review protocols, the identification of underutilization and overutilization of services, and the availability of information on quality and outcome measures as needed to facilitate beneficiary comparisons and choices among M+C plans.

b. Performance Measurement and Reporting. Section 422.152(c) elaborates on paragraph (b)(1) by requiring that the organization: (1) measure and report its performance to HCFA using measures required by HCFA, and (2) for M+C coordinated care plans, achieve any minimum performance levels that may be established locally, regionally, or nationally by HCFA. The first requirement is based directly on the requirement under section 1852(e)(2)(A)(i) of the Act concerning outcome measurement and reporting. Thus, it applies both to M+C coordinated care plans and network MSA plans (as well as to M+C non-network MSA plans and PFFS plans, as discussed below in section II.D.2.d of the preamble). The second requirement enables HCFA to evaluate a plan's ability to meet the objectives of sections 1852(e)(2)(A)(x) and (xi) of the Act concerning quality assessment and improvement. It also reflects HCFA's responsibility to require that the services we purchase meet minimum quality standards. (We note that although the requirements of sections 1852(e)(2)(A)(x) and (xi) of the Act apply to M+C network MSA plans as well as to M+C coordinated care plans, we are not requiring in this interim final rule that M+C network MSA plans achieve minimum performance levels. In keeping with the demonstration status of the M+C MSA plans, we intend to evaluate the performance of these plans in the context of the evaluation provisions of section 1851(b)(4)(B) of the Act.)

Health plan performance measurement and reporting is in its early stages. Consensus regarding what aspects of plan performance can and should be measured, how this information should be reported, how it should be audited, and which measures are collectible for which types of organizations, is only now being developed. HCFA, large private purchasers, managed care organizations, and others have made important progress in defining and measuring health plan performance. This regulation must move us toward enhancing health plan accountability while leaving flexibility for the specific reporting and performance requirements to progress as we learn more about performance measurement. We want to be able to respond rapidly to new developments in the state of the art of quality measurement and improving performance levels.

We do not intend to adopt a ''one size fits all'' approach that assumes that reporting under all types of M+C plans will be possible in the same manner for all measures. We will balance our efforts to increase uniformity to facilitate consumer comparison of plans with sensitivity to the different organizational structures of plans and their different abilities to affect provider behavior.

In general, an M+C organization should not be held accountable for improving services that it does not promise to provide under a plan, nor for reporting information to which it does not reasonably have access under a plan. At the same time, an organization should be held accountable for improving plan performance with respect to the benefits provides under the M+C program and all applicable M+C standards, and for having the information needed to maintain and improve the quality of the services it delivers or arranges for. Organizations should be expected to improve their capacity to collect and analyze information about the delivery of M+C benefits, consistent with changes that are occurring in the health plan market place. We believe that Congress intended us to take the actions that any prudent purchaser would take to hold M+C organizations accountable for the benefits they promise to provide under a plan.

For these reasons, we are not specifying the particular measures for which reporting will be required or the minimum performance levels that M+C coordinated care plans will be expected to achieve. Instead, the regulation clarifies the general clinical and nonclinical areas to be addressed by the performance reporting, such as effectiveness of care, use of services, and access to services. The performance measures to be reported and the minimum performance standards that the M+C plan or plans offered by an organization will be required to meet will be addresses on an organization and plan-specific basis, as described below.

Section 422.152(c)(1) establishes that standard performance measures may be specified in data collection and reporting instruments required by HCFA. For example, as mentioned earlier, HCFA has already begun requiring reporting of standardized quality measurement data through instruments such as HEDIS © 3.0, as well as reporting of standardized consumer satisfaction data through the Consumer Assessment of Health Plans Study (CAHPS). We expect that in contract year 1999, the standard performance measures for M+C organizations will include most HEDIS measures and a member survey, with the possibility of additional measures. (Where data on particular measures are not reasonably available with respect to a given plan, organizations can report ''not available''. HCFA will work with M+C organizations to identify those measures for which data are and are not reasonably available for a given plan.) To the extent that we do include HEDIS measures, we will use the HEDIS measurement specifications. Before the beginning of the next contract year, we will decide on the measures on which reporting will be required for contract year 1999 and will notify organizations of those measures through the contracting process.

We expect to develop a core set of measures on which reporting will be required under all plans. We also expect to identify additional reporting requirements to reflect the plan's characteristics (such as supplemental benefits, type of delivery system) and past performance.

In adopting minimum performance requirements for coordinated care plans, we intend to ensure that the targets are achievable, meaningful, and equitable. We intend to move toward minimum uniform national performance standards

based on what plans across the nation are able to achieve.

We expect to start with standards that are adjusted to reflect performance in the plan's region and the individual plan's or organization's historical performance (or performance in Medicare fee-for-service where the plan has no history). Performance requirements will be established only for measures for which there are sufficient historical data available to establish regional standards based on actual performance of a number of plans. (We will therefore require reporting on measures for which performance standards have not been established.) Other criteria will also guide the selection of measures for which minimum performance levels will be established, including their significance for the health of the enrolled population under a plan and the likelihood that they fairly reflect the organization's performance.

Because the process of identifying achievable, meaningful and equitable minimum performance levels will require a significant amount of data collection and analysis, we expect that it will be several years before a full complement of minimum performance levels can be established. At this point, it is uncertain whether any minimum performance levels will be established for the 1999 contract year. We will identify minimum performance levels on a measure by measure basis, after evaluating baseline data and the distribution of organization performance and considering potential opportunities for improvement. The process of identifying minimum performance levels will evolve as new methods of performance measurement develop.

HCFA is committed to public involvement in the selection of measurement topics. HCFA will also work collaboratively with organizations involved with quality and performance standards and measurements, including performance measurement experts, health plans, public and private purchasers and beneficiary representatives in the selection of specific measures and setting of minimum performance levels. As we develop minimum performance standards, we will consider how our goal of maintaining maximum consumer choice in the M+C program should affect our expectations concerning plan performance.

When we have identified minimum performance levels, we plan to establish them prospectively upon contract initiation and renewal, so that an organization will have the entire contract year in which to take action to meet them. By the end of the contract year, the organization must meet any identified minimum performance levels. In some cases, we believe that the next contract year will have already begun by the time HCFA learns whether the organization has met the minimum performance levels established for the previous year. Therefore, we specify that HCFA may decline to renew an organization's contract in the year that HCFA determines that the organization failed to meet the minimum performance levels, even if the failure itself was in the prior contract year.

c. Performance Improvement Projects. Section 422.152(d) establishes the requirements for performance improvement projects, beginning with the requirement that performance improvement projects focus on specified areas of clinical and nonclinical services. It also explains that HCFA will set M+C organizational and plan-specific requirements for the number and distribution of these projects among the required areas. In addition, it authorizes HCFA to direct an M+C organization to undertake specific performance improvement projects and participate in national and State-wide performance improvement projects. Section 422.152(d) reflects many of the provisions of section 1852(e)(2) of the statute, including for example the requirements for projects in areas such as high-volume and high-risk services and continuity and coordination of care (sections 1852(e)(2)(A)(ii) and (iii), respectively).

Section 422.152(d)(1) explains what is meant by a project. All projects must involve the measurement of performance, system interventions (including the establishment or alteration of practice parameters), improving performance, and systematic follow-up on the effect of the interventions.

Section 422.152(d)(2) requires that projects address the entire population to which the performance measure is relevant. Thus, once a topic has been selected, the organization must assure that its measurement and improvement efforts are at least plan-wide. (Note that we do not intend to prohibit an M+C organization from conducting performance improvement projects that would cut across plans.) We expect that, to the extent feasible, each project should reach all enrollees and providers in the plan network who are involved in the aspect of care or services to be studied. This does not mean that a project must involve review of the performance of each provider who furnishes the services that are the subject of the project, or that it must survey every affected enrollee. Sampling is acceptable if the organization can demonstrate that its samples are genuinely random. An organization could do so by showing, for example that:

- Each relevant provider and enrollee has a chance of being selected; no provider or enrollee is systematically excluded from the sampling.
- Each provider serving a given number of enrollees has the same probability of being selected as any other provider serving the same number of enrollees.
- Providers and enrollees who were not included in the sample for the baseline measurement have the same chance for being selected for the follow-up measurement as providers and enrollees who were included in the baseline.

Section 422.152(d)(3) states that HCFA will establish M+C organizational and M+C plan-specific obligations for the number and distribution of projects among the required clinical and non-clinical areas. Sections 422.152(d)(4) and (5) then specify the minimum clinical and nonclinical focus areas that must be addressed through these projects. These minimum focus areas are:

- Clinical areas—prevention and care of acute and chronic conditions; high volume services and high risk services; continuity and coordination of care.
- Nonclinical areas: appeals, grievances, and other complaints; access and availability of services.

Note that these areas represent minimum requirements, and organizations are likely to carry out projects in other areas in order to meet their contractual performance improvement obligations. The length of the performance improvement cycle, that is, the period of time during which an organization must conduct a project that demonstrates improvement in each of the required focus areas, will be one of the contractual performance improvement obligations. Within each clinical and nonclinical focus area, an organization will have considerable freedom to select its own particular topics for measurement and improvement, so that it can initiate projects relating to aspects of care and services that are significant for its plan-specific population. Our goal is to achieve a balance between encouraging flexibility and innovation and ensuring that every organization conducts meaningful projects over a broad spectrum of care and services. As noted above, however, there may be instances where it is necessary for HCFA to direct the organization to address a specific

topic within a given focus area. Thus, § 422.152(d)(6)(i) provides that, in addition to requiring that an organization initiate its own performance improvement projects, HCFA may direct an organization to conduct particular performance improvement projects that are specific to the organization. We believe this could be necessary, for example, when an organization demonstrates a significant weakness in a particular performance area, but the area is not addressed in the organization's own performance improvement projects. Similarly, § 422.152(d)(6)(ii) provides that HCFA may require an organization to participate in national or statewide performance improvement projects. These performance improvement projects would focus on aspects of care that we believe are of high priority, and would be designed by HCFA (or possibly by other entities, such as the external quality review organizations affiliated with Medicaid managed care organizations).

In general, we believe that when an organization initiates a project, the clinical or nonclinical issue selected for study should affect a substantial portion of the plan's M+C enrollees (or a specified subpopulation of enrollees) and have a potentially significant impact on enrollee health, functional status, or satisfaction. There may be instances in which less frequent conditions or services warrant study, as when data show a pattern of unexpected adverse outcomes; however, the prevalence of a condition or volume of services involved should be sufficient to permit meaningful study.

A project topic may be suggested by patterns of inappropriate utilization—for example, frequent use of the emergency room by enrollees with a specific diagnosis. However, the project should be focused clearly on identifying and correcting deficiencies in care or services that might have led to this pattern, such as inadequate access to primary care, rather than on utilization and cost issues alone. This is not to say that an organization may not make efforts to address overutilization, but only that such efforts may not meet the requirements of § 422.152, unless the primary objective is to improve outcomes. Thus, it would be acceptable for a project to focus on patterns of overutilization that present a clear threat to health or functional status, for example, a high risk of iatrogenic problems or other adverse outcomes.

Because the achievement of demonstrable improvement is a central criterion in the evaluation of projects, the projects should necessarily address areas in which meaningful improvement can be effected through system interventions by the organization. Thus, organizations should focus on areas in which there is significant variation in practice and resulting outcomes within a plan, or in which performance as a whole falls below acceptable benchmarks or norms.

Organizations are encouraged to undertake complex projects or innovative projects that have a high risk of failure but that offer potential for making a significant difference in the health or functional status of enrollees. We recommend that M+C organizations look to the independent quality review and improvement organizations with which they have agreements (see the discussion below about the external review requirements of § 422.154) for assistance in designing and executing performance improvement projects.

Section 422.152(d)(7) requires that an organization assess performance for each project using one or more quality indicators, that are objective, clearly defined, and based on current clinical knowledge or health services research. In accordance with the emphasis section 1852(e)(2)(A)(i) places on outcomes, the regulation requires that the quality indicators measure outcomes such as changes in health status, functional status, and enrollee satisfaction, or measure valid proxies of these outcomes. We recognize that relatively few existing standardized performance measures actually address outcomes. For example, of the 16 effectiveness measures in HEDIS 3.0, only one (health of seniors) is truly outcome-based. Even when outcome measures are available, their utility as quality indicators for projects may be limited if the outcomes are dictated largely by factors outside the organization's control.

Therefore, we do not require that quality indicators be limited to outcome measures. Process measures are acceptable so long as the plan can show that they are valid proxies, that is, there is strong clinical evidence that the process being measured is meaningfully associated with outcomes. To the extent possible, this determination should be based on published guidelines that support the association and that cite evidence from randomized clinical trials, case control studies, or cohort studies. An M+C organization may furnish its own similar evidence of association between a process and an outcome, as long as this association is not contradicted by a published guideline. Although published evidence is generally required, there may be certain areas of practice for which empirical evidence of process/outcome linkage is limited. At a minimum, an organization should be able to demonstrate that there is a consensus among relevant practitioners as to the importance of a given process.

While we consider enrollee satisfaction an important aspect of care, improvement in satisfaction may not be the sole demonstrable outcome of a project in any clinical focus areas. Some improvement in health or functional status must also be measured. (Note that this measurement can rely on enrollee surveys that address topics in addition to satisfaction. For example, self-reported health status may be an acceptable indicator.) For projects in the nonclinical areas, use of health or functional status indicators is generally preferred, particularly for projects addressing access and availability. However, there may be some nonclinical projects for which enrollee satisfaction indicators alone are sufficient.

Section 422.152(d)(8) requires that performance assessment be based on systematic, ongoing collection and analysis of valid and reliable data. Data will most commonly be derived from administrative data generated by an organization's health information system or from review of medical records. (In assessing nonclinical services, other sources such as enrollee or provider surveys may be appropriate.) When data are derived from the health information system, their reliability is obviously a function of the general reliability of the system. When data are derived from direct review of medical records or other primary source documents, steps must be taken to assure that the data are uniformly extracted and recorded. Appropriately qualified personnel must be used; this will vary with the nature of the data being collected and the degree of professional judgment required. We expect there to be clear guidelines or protocols for obtaining and entering the data; this is especially important if multiple reviewers are used or if data are collected by multiple subcontractors. Inter-reviewer reliability should be assured through, for example, repeat reviews of a sample of records.

Section 422.152(d)(9) requires that interventions achieve improvement that is significant and sustained over time. In general, we will judge improvement to be significant when a benchmark level of performance is achieved in the percentage of enrollees who exhibit a negative outcome defined by the indicator.

Again, specific acceptable performance measures will be defined for each M+C organization and M+C

plan. Currently, we are considering requiring a 10 percent reduction in negative outcomes as evidence of significant improvement. An organization would meet this requirement if, for example, its flu immunization rate under a plan is 80 percent in the baseline and increases to 82 percent, because the percentage of enrollees *not* immunized has dropped from 20 percent to 18 percent, a 10 percent reduction. A plan whose baseline rate was 60 percent would have to reach 64 percent (a reduction in nonimmunized enrollees from 40 percent to 36 percent).

We are considering requiring a 10 percent reduction in adverse outcomes as evidence of significant improvement for several reasons. First, the use of a constant percentage reflects the likelihood that change is harder to achieve when an organization's baseline performance is already superior. Thus, under a plan with an 80 percent immunization rate, we would expect a 2 percentage point improvement, while under a plan with a 60 percent rate, a 4 percentage point improvement would be expected. Second, the 10 percent level is consistent with results HCFA has observed in successful improvement projects sponsored by the agency. Finally, we believe that smaller improvements would generally be of little clinical significance. We invite comment on the issue of whether § 422.152(d)(9) should be revised to provide for a 10 percent reduction in adverse outcomes.

Note that improvement in an *indicator* is not necessarily the same as improvement in the health or functional status of enrollees. For example, the ''health of seniors'' indicator under HEDIS 3.0 will track, over time, changes in the functional status of elderly enrollees. Each enrollee's functional status may remain stable or actually decline. However, an organization would demonstrate improvement on the indicator if it slowed the rate of decline, whether or not it actually improved enrollees' functional status. HCFA is considering judging improvement to be sustained under a plan if it can be demonstrated through continued measurement that performance gains have endured for at least one year.

We recognize that many organizations still have limited experience in conducting well-designed performance improvement projects, and that any given project may take some time to produce measurable improvement. Therefore, we intend to permit a gradual phase-in of the number of focus areas for which improvement must be demonstrated consistent with the individual circumstances of an M+C organization.

Section 422.152(d)(10) concludes the performance improvement requirements by providing explicitly that an organization must report the status and results of each project to HCFA upon request. This requirement is necessary to implement the reporting requirements embodied in sections 1852(e)(2)(A)(vi) and (xii) and 1851(d)(4)(D) and (d)(7), which call for HCFA to make available to M+C eligible individuals information comparing M+C plan options, including information on quality and performance.

d. Requirements for M+C Private Fee-for-Service and Non-Network MSA Plans. In enacting the quality assurance provisions of the BBA, Congress recognized that not all of the quality assessment and performance improvement activities that are appropriate for a plan with a defined provider network would be appropriate for an M+C non-network MSA plan or an M+C private fee-for-service plan. (Section 1852(e)(2)(C) defines a non-network MSA plan as an MSA plan that does not provide any of the covered benefits through a defined set of providers under contract to the organization or under arrangements made by the organization, and we have incorporated this provision into § 422.4(a)(2)(ii).) As a result, section 1852(e)(2)(B) establishes different required elements of a quality assessment and performance improvement program depending on the type of plan involved. Specifically, the Act exempts M+C non-network MSA and PFFS plans from the requirements of paragraphs (e)(2)(A)(vii) through (xii) of section 1852, which include the utilization review requirements discussed above as well as the explicit requirement to take action to improve quality and assess the effectiveness of such action through systematic follow-up. However, the statute continues to require that organizations offering these types of plans stress outcomes, provide for the data collection, analysis, and reporting necessary to measure outcomes, and monitor and ensure the quality of care they provide.

Consistent with the statute, the specific requirements to achieve minimum performance levels and undertake performance improvement projects will not apply to M+C non-network MSA and PFFS plans. Both requirements are derived primarily from the statutory requirements from which these types of plans have been exempted (that is, sections 1852(e)(2)(A)(x) and (xi). Instead, we have established separate requirements that apply for these types of plans under § 422.152(e). These requirements parallel the requirements for other types of plans to the extent permitted under the statute. For example, § 422.152(e)(1) requires that under these plans, an organization must measure its performance, using standard measures established or adopted by HCFA. These measures will focus on the prevention and care of acute and chronic conditions, high-volume and high-risk services, and enrollee satisfaction. We invite comment on whether additional areas for standard measures should be added to § 422.152(e)(1). Section 422.152(e)(2) requires evaluation of the continuity and coordination of care that enrollees receive. Together, the requirements under § 422.152(e)(1) and (2) reflect the requirements of paragraphs (e)(2)(A)(i), (ii), (iii), and (v) of section 1852.

Sections 1852(e)(2)(B)(ii) and (iii) specify that if an M+C non-network MSA or PFFS plan has written protocols for utilization review, those protocols must be based on current standards of medical practice, and have mechanisms to evaluate utilization services and inform providers and enrollees of the results of such evaluation. These requirements are incorporated into § 422.152(e)(3).

e. *Requirements for All Plans: Health Information.* In order to support the measurement of performance levels and the conduct of its performance improvement projects, if applicable, all plans must maintain a health information system that collects, analyzes, integrates, and reports data. This requirement is covered at § 422.152(f). Although an encounter data system may often be the most efficient means of meeting the requirements of this standard, the plan may use any methods or procedures for the collection of quality data, so long as it can demonstrate that its system achieves the objectives of the requirement.

The strategy of relying on performance measurement and performance standards to assess and improve quality is heavily dependent on the validity of the data collected and reported by plans. Therefore, § 422.152(f)(1)(ii) requires that an organization ensure that the information received from its providers is reliable and complete. If the organization receives individual encounter data directly from providers, it must have a system for comparing reported data to a sample of medical records, to verify the accuracy and timeliness of reporting or transmission. The objective is to assure that, to the extent feasible, there is a

one-to-one correspondence between items included in an organization's summary data and specific services entered in medical records or equivalent source documents. (That is, no reported service was not performed, and no service performed was not reported.) If the organization receives aggregate information, instead of individual patient encounter reporting, from any provider, under a plan the organization must approve the provider's own system for collecting, recording, aggregating, and reporting the data, and must assure that the provider has its own mechanisms for validation. Identified deficiencies in reported data should be addressed through provider education or other corrective action. The organization's process for recredentialing or recontracting with practitioners and providers should specify the actions to be taken in the event of ongoing failure by a contractor to meet the organization's health information standards.

In addition to requiring that the information collected be accurate and complete, § 422.152(f)(1)(iii) requires that the organization make all information collected available to HCFA. This requirement reflects section 1852(e)(2)(A)(vi), which recognizes that HCFA cannot adequately monitor and ensure the quality of health care services without access to appropriate information. For example, access to this information will allow HCFA to validate the accuracy and completeness of the information and to evaluate performance improvement projects. Note that although HCFA may disclose whether an organization has met its requirements for performance improvement, we will not make public the results of an organization's performance improvement projects, as these results may involve enrollee-specific information.

f. *Program Review.* Section 422.152(f)(2) requires that for each plan an organization have a process for formal evaluation, at a minimum annually, of the impact and effectiveness of the quality assessment and performance improvement program strategy. The evaluation should assess both the progress in implementing the strategy and the extent to which the strategy is in fact promoting the development of an effective quality assessment and performance improvement program. It should consider whether quality-related activities in the organization's workplan are being completed on a timely basis or whether commitment of additional resources is necessary. The evaluation should include recommendations for needed changes in program strategy or administration. These recommendations should be forwarded to and considered by the policymaking body of the organization. These requirements reflect the evaluation provisions of section 1852(e)(2)(A)(iv).

4. External Review (§ 422.154)

Section 1852(e)(3) requires, subject to the exceptions discussed below, that each M+C organization, for each M+C plan it operates, have an agreement with an independent quality review and improvement organization (review organization) approved by HCFA to perform functions of the type described in part 466 of chapter 42, which establishes review responsibilities for utilization and quality control Peer Review Organizations (PROs). This requirement appears in § 422.154(a).

PROs are physician-sponsored or physician-access organizations that review services ordered or furnished by other practitioners in the same professional field for the purpose of determining whether such services are or were reasonable or medically necessary, and whether the quality of such services meets professionally recognized standards of health care. Because PROs generally are already accomplished at the activities the statute requires of review organizations, HCFA will approve as review organizations the PROs and PRO-like entities who are currently under contract with HCFA to perform the functions of part 466. The current PRO contract will expire on March 31, 1999. The entities awarded the next contract, known as the Sixth Scope of Work, will be approved to serve as review organizations as of April 1, 1999.

An important element of both the current and next contract is a strategy to continuously improve quality of care and strengthen the ability of health care organizations and practitioners to assess and improve their own performance. Under this strategy, known as the Health Care Quality Improvement Program, part 466 contractors use statistical information to examine medical processes and outcomes of health care and provide feedback to providers so that this information can be used to benchmark progress toward improved practice and outcomes.

HCFA will establish guidelines for the agreements between M+C organizations and review organizations modeled on the guidelines found in part 466. The guidelines will specify that an M+C organization must allocate adequate space for the review organization to carry out its review (during the period of the review); and that the organization must provide enrollee care data and other pertinent data to the review organization on a timely basis as needed to facilitate making its determinations. These requirements appear in § 422.154(b)(1).

With respect to M+C non-network MSA and PFFS plans, for which utilization review is not a requirement, section 1852(e)(3)(A) of the statute exempts organizations from the requirement that there be an agreement with a review organization. Section 1852(e)(3)(B) also provides an exemption for review organization activities with respect to accredited plans that HCFA determines would be duplicative of activities conducted as part of the accreditation process. In the case of review of quality complaints, this exemption does not apply, however, and the requirement for investigation by the review organization would apply even with respect to an accredited plan. This exemption appears in § 422.154(b)(2). While the statute only mandates that the Secretary exempt accredited plans from the duplicative review by review organizations, we believe that the same logic extends to review activities that would be duplicative of HCFA monitoring review. Thus, pursuant to our general authority under section 1856(b)(1) to establish standards under Part C, we are providing in § 422.154(b)(2) that M+C organizations are also exempt from review by a review organization that would be duplicative of HCFA monitoring review.

Under section 1852(e)(3)(C), HCFA may waive the requirement that an M+C organization have an agreement with a review organization if HCFA determines that an organization has consistently maintained an excellent record of quality assessment and performance improvement and compliance with the other requirements of this part. As discussed in detail above, § 422.152 establishes requirements for a plan's quality assessment and performance improvement (QAPI) program. After the rule is effective, and HCFA has had the opportunity to assess QAPI implementation, we will be in a position to establish waiver criteria, which we intend to promulgate through notice and comment rulemaking.

5. Deemed Compliance Based on Accreditation (§§ 422.156 Through 422.158)

a. *Compliance Deemed on the Basis of Accreditation (§ 422.156).* Section 1852(e)(4) gives HCFA the authority to deem that an M+C organization meets certain requirements if the M+C organization is accredited and

periodically reaccredited by a private organization under a process that HCFA has determined ensures that the M+C organization, as a condition of accreditation, meets standards that are no less stringent than the applicable HCFA requirements. We do not believe that HCFA could effectively determine whether a potentially unlimited number of small, regional accreditation organizations meet the standard in section 1852(e)(4). Section 422.156 accordingly limits the deeming provided for under section 1852(e)(4) to national accreditation organizations. National accreditation organizations are those that offer accreditation services that are available in every State to every organization wishing to obtain accreditation status.

The process that HCFA will use to deem compliance with M+C requirements will mirror the process used for deeming compliance with fee-for-service requirements, because that process is equally applicable to the managed care setting. Therefore, many of the requirements of this section, as well as those in §§ 422.157 and 422.158, are essentially restatements of their fee-for-service equivalents in subpart A of part 488 of existing Medicare regulations.

Section 422.156(a) specifies the conditions under which an M+C organization may be deemed to meet the HCFA requirements permitted to be deemed under section 1852(e)(4). (These requirements are identified in the regulations at § 422.156(b).) The first condition is that the M+C organization be fully accredited (and periodically reaccredited) by a private, national accreditation organization approved by HCFA. Only full accreditation offers HCFA adequate assurance that the M+C organization meets the applicable HCFA requirements. M+C organizations that are conditionally or provisionally accredited (or the equivalent thereof) by their accreditation organization do not meet all of their accreditation organization's requirements, and for this reason, will not be deemed to meet the HCFA requirements. The second condition is that the M+C organization be accredited using the standards approved by HCFA for the purposes of assessing the M+C organization's compliance with Medicare requirements. Given that certain accreditation organizations have multiple accreditation processes (for example, other product lines aside from their Medicare product line), this requirement is necessary to ensure that only M+C organizations with the appropriate accreditation are deemed to meet HCFA requirements.

Section 422.156(b) specifies the requirements that may be deemed. In accordance with the statute, these include the quality assessment and performance improvement requirements of § 422.152, and the requirements of § 422.118 related to confidentiality and accuracy of enrollee records. An M+C organization accredited by an approved accreditation organization may be deemed to meet any or all of these requirements, depending on the specific requirements for which its accreditation organization's request for approval was granted.

Given the complexity and breadth of the benefits and services offered under the M+C program, we believe that we should analyze the standards applied by accreditation organizations on a standard-by-standard basis. In the past, in the context of original fee-for-service Medicare, we have taken an ''all or nothing'' approach in approving accreditation organizations. If an organization was approved, it was approved for purposes of all requirements, and all requirements were accordingly deemed. Since section 1852(e)(4) refers to deeming of ''the requirements involved,'' however, we intend under this authority to determine on a standard-by-standard basis whether an accreditation organization applies and enforces requirements no less stringent than those in part 422 with respect to the standard at issue. We will determine the scope of the accreditation organization's approval (and thus the extent to which M+C organizations accredited by the organization are deemed to meet HCFA requirements) based on a comparison of the accreditation organization's standards, and its procedures for assessing compliance, with the deemable HCFA requirements and our own decision-making standards.

As mentioned above, the requirements that may be deemed are the quality assessment and performance improvement requirements of § 422.152, and the confidentiality and accuracy of enrollee records requirements of § 422.118. We will approve an accreditation organization only for those requirements for which it applies and enforces standards that are as least as stringent as the HCFA requirements. For instance, § 422.152(e) requires that an M+C organization conduct performance improvement projects that achieve significant and sustained improvement. An accreditation organization will not be approved for this requirement unless we determine that, as a condition of accreditation, the accreditation organization's requirements concerning the conduct of performance improvement projects are as rigorous as the HCFA requirements, with a similar emphasis on outcomes. We will make such determinations on the basis of the application materials submitted by accreditation organizations seeking HCFA approval in accordance with § 422.158. We would also do surveys to validate the accreditation organization's enforcement on a standard-by-standard basis.

Section 422.156(c) establishes when deemed status is effective. Deemed status is effective on the later of the following dates: the date on which the accreditation organization is approved by HCFA, or the date that the M+C organization is accredited by the accreditation organization.

Section 422.156(d) establishes the obligations of deemed M+C organizations. An M+C organization deemed to meet Medicare requirements must submit to surveys to validate its accreditation organization's accreditation process, and authorize its accreditation organization to release to HCFA a copy of its most current accreditation survey, together with any information related to the survey that HCFA may require (including corrective action plans and summaries of unmet HCFA requirements.) These two activities are part of HCFA's ongoing oversight strategy for ensuring that the accreditation organization applies and enforces its accreditation standards in a manner comparable to HCFA's.

Section 422.156(e) addresses removal of deemed status. HCFA will remove part or all of an M+C organization's deemed status if: (1) HCFA determines, on the basis of its own survey or the results of the accreditation survey, that the M+C organization does not meet the Medicare requirements for which deemed status was granted; (2) HCFA withdraws its approval of the accreditation organization that accredited the M+C organization; or (3) the M+C fails to meet the requirements of paragraph (d) of this section.

The final paragraph, § 422.156(f), explains that HCFA retains the authority to initiate enforcement action against any M+C organization that it determines, on the basis of its own survey or the results of the accreditation survey, no longer meets the Medicare requirements for which deemed status was granted. We expect the accreditation organization to have a system in place for enforcing compliance with its standards, perhaps sanctions for motivating correction of deficiencies, but HCFA cannot delegate to the accreditation organization the authority to impose the intermediate

sanctions established by section 1857(g) or termination of the M+C contract.

b. *Accreditation organizations (§ 422.157).* This section of the regulation discusses three conditions for HCFA approval of an accreditation organization. HCFA may approve an accreditation organization if the organization applies and enforces standards for M+C organizations that are at least as stringent as Medicare requirements (as discussed above); the organization complies with the application and reapplication procedures set forth in § 422.158, ''Procedures for approval of accreditation as a basis for deeming compliance;'' and, the organization is not controlled by the managed care organizations it accredits, as defined at 42 CFR 413.17. Control exists if the accredited organizations have the power, directly or indirectly, to significantly influence or direct the activities or policies of the accreditation organization. We have included this requirement to preclude any conflict of interest that should compromise the integrity of the accreditation process.

Section 422.157(b) describes notice and comment procedures. Because the approval of an accreditation organization could have broad impact upon large numbers of organizations, providers, and consumers, we are providing notice and comment opportunities similar to those provided in the fee-for-service arena. HCFA will publish a proposed notice in the Federal Register whenever it contemplates approving an accreditation organization's application for approval. The proposed notice will specify the basis for granting approval; describe how the accreditation organization's accreditation program meets or exceeds all of the Medicare requirements for which HCFA would deem compliance on the basis of accreditation; and provide opportunity for public comment. HCFA will publish a final notice in the Federal Register whenever it grants an accreditation organization's request for approval. Publication of the final notice will occur after HCFA has reviewed the public comments received in response to the proposed notice. The final notice will specify the effective date of the approval, and the term of approval, which will not exceed 6 years.

Section 422.157(c) establishes ongoing accreditation organization responsibilities. These responsibilities largely parallel those currently imposed upon accreditors under original Medicare. One exception is the requirement at § 422.157(c)(4) that an accreditation organization notify HCFA in writing within 3 days of identifying, with respect to an accredited M+C organization, a deficiency that poses immediate jeopardy to the M+C organization's enrollees or to the general public. Although the existing counterpart for this requirement under original Medicare (§ 488.4(b)(3)(vii)) allows an accreditation organization 10 days to provide this notice, we believe that a 3-day time period will better enable HCFA to take any necessary action to protect the health and safety of enrollees or the general public in a situation that poses immediate jeopardy. (Note that we also intend to address this issue in our planned comprehensive revision of the deeming requirements under original fee-for-service Medicare.)

Section 422.157(d) establishes specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization. Oversight consists of equivalency review, validation review, and onsite observation.

Equivalency review. HCFA compares the accreditation organization's standards and its application and enforcement of those standards to the comparable HCFA requirements and processes when HCFA imposes new requirements or changes its survey process; an accreditation organization proposes to adopt new standards or changes in its survey process; or the term of an accreditation organization's approval expires.

Validation review. HCFA or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey, in order to validate the organization's accreditation process. At the conclusion of the review, HCFA identifies any accreditation programs for which validation survey results indicate (1) a 20 percent rate of disparity between certification by the accreditation organization and certification by HCFA or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet; or (2) indicate any disparity at all on standards that constitute immediate jeopardy to patient health and safety if unmet. Our beneficiary-centered approach to managed care oversight dictates zero tolerance of accreditation organization failures to identify noncompliance that expose beneficiaries to such serious risks. At the conclusion of a validation review, HCFA also identifies any accreditation programs for which validation survey results indicate, irrespective of the rate of disparity, that there are widespread or systematic problems in an organization's accreditation process such that accreditation no longer provides assurance that the Medicare requirements are met or exceeded. Accreditation programs identified as noncompliant through validation review may be subject to withdrawal of HCFA approval.

Onsite observation. HCFA may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, reviewing documents, auditing meetings concerning the accreditation process, evaluating survey results or the accreditation status decision making process, and interviewing the organization's staff.

Notice of intent to withdraw approval. If a comparability review, validation review, onsite observation, or HCFA's daily experience with the accreditation organization suggests that an accreditation organization is not meeting the requirements of this subpart, HCFA gives the organization written notice of its intent to withdraw approval.

HCFA may withdraw its approval of an accreditation organization at any time if we determine that deeming based on accreditation no longer guarantees that the M+C organization meets the Medicare requirements, and failure to meet those requirements could jeopardize the health or safety of Medicare enrollees or constitute a significant hazard to the public health; or the accreditation organization has failed to meet its obligations under §§ 422.156, 422.157, 422.158.

The final provision of § 422.157(d) addresses reconsideration. An accreditation organization dissatisfied with a determination to withdraw HCFA approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter.

c. *Application and reapplication procedures for accreditation organizations (§ 422.158).* As mentioned, the process that HCFA will use to deem compliance with M+C requirements is virtually identical to the process that is being used for deeming compliance with fee-for-service requirements. This section of the regulation is modeled on § 488.4, ''Application and reapplication procedures for accreditation organizations.'' One requirement that appears in § 422.158 does not appear in § 488.4 is the requirement that an

accreditation organization applying for approval of deeming authority submit the name and address of each person with an ownership or control interest in the accreditation organization. Such information will be used to determine whether the accreditation organization is controlled by the organizations it accredits, for the purposes of § 422.157. The remaining requirements of this section, which pertain to other required information and materials, the mechanics of the approval process, and the reconsideration of an adverse determination, are essentially restatements of the requirements of § 488.4.

E. Relationships With Providers

Subpart E focuses on requirements for relationships between M+C organizations and health care professionals with whom they contract or enter agreements to provide services to Medicare beneficiaries enrolled in an M+C plan. These requirements encourage communication, coordination, and cooperation between organizations and health care professionals on plan rules and policies. This subpart also includes other new provider protections enacted as part of the BBA; incorporates provisions affecting health professionals that are consistent with the recommendations contained in the Consumer Bill of Rights and Responsibilities, as recommended by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, the model act adopted by the National Association of Insurance Commissioners, credentialing standards of nationally accepted accrediting bodies, and QISMC standards; and incorporates policies already applicable to provider and plan relationships included in the current part 417 or other policy issuances. In February 1998, an executive order was issued directing the Secretary to comply to the extent possible through administrative activities with the standards contained within the Consumer Bill of Rights presented to the President in November 1997. Many of the issues were addressed in the BBA and implementation of the regulations will expand compliance with the directive.

1. Participation Procedures (§ 422.202)(a))

Section 1852(j)(1) requires an M+C organization that offers benefits under an M+C plan through agreements with physicians to establish reasonable procedures relating to their participation under the plan. This is a new federal requirement for Medicare contracting managed care organizations. Current rules in part 417 do not mandate that HMOs/CMPs adopt provider participation rules. However, some Medicare contractors have adopted provider participation policies in response to state laws or plan policies.

We are interpreting this provision to apply to all M+C organizations that operate M+C plans providing benefits through a limited network of contracting health care professionals or groups of health care professionals, that is, all types of M+C coordinated care plans, such as HMOs, PPOs, etc., as well as network M+C MSA plans. In the case of M+C private fee-for-service plans and non-network M+C MSA plans, there are no limits on the number of health professionals who may provide services covered under the M+C plan, as long as they accept the plan's terms and conditions for payment. These plans in essence operate on an ''any willing provider'' approach to which the procedures in section 1852(j)(1) would not be relevant. Since any provider has the right to participate, rules requiring a notice of adverse participation decisions, and appeals from such decisions could have no applicability. It also would not be feasible to provide the notices required under section 1852(j)(1) and § 422.202(a) (discussed below) to the virtually unlimited number of providers who would be entitled to provide services to a M+C private fee-for-service or non-network M+C MSA plan enrollees.

The statutory requirements in section 1852(j)(1) focus on three procedural aspects—ensuring that providers are aware of the plan participation rules; requiring written notice when participation decisions are adverse; and affording the provider an opportunity to appeal adverse plan participation decisions. The statute specifies that these procedures apply to plan relationships with physicians. In reviewing the model act of the National Association of Insurance Commissioners (NAIC), QISMC standards, and many state laws and regulations, we found that these procedural protections generally have been applied to all health care professionals who are responsible for delivering services to beneficiaries of the plan, not just physicians. Since Medicare-payments can be made to practitioners other than physicians and since M+C organizations may furnish services utilizing a range of licensed health care professionals, we believe it is appropriate to apply these requirements to all health care professionals if coverage for their services is provided under the M+C plan. For purposes of § 422.202 and § 422.204, these include, but are not limited to, a physician, podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist, speech-language pathologist, audiologist, nurse practitioner, clinical nurse specialist, certified nurse anesthetist, and certified nurse-midwife and licensed certified social worker. Thus, under our authority under section 1856(b)(1) to establish standards for M+C organizations, § 422.202 requires that all professionals as listed above should be provided with rules of participation, written notices of participation decisions and an appeal process.

With regard to types of procedures that are subject to disclosure, written notification and appeal requirements, we are adopting a broad definition of procedures that might affect participation in the plan or network. In § 422.202 we specify that procedural requirements should include any rules that affect the process of direct delivery of services by a health professional to a Medicare beneficiary. The examples include terms of payment, utilization review, quality improvement programs, credentialing, data reporting, confidentiality, guidelines or criteria for furnishing services, and other rules related to administrative policy. All of these procedures affect how a health care professional would participate in a plan and should therefore be divulged up front prior to a health care professional's agreement to participate in the plan. In addition, we believe that full disclosure in advance, to potential participating health care professionals, of the broad range of procedures relating to participation should reduce subsequent challenges or appeals. While the disclosure requirement in § 422.202(a)(1) does not apply directly to M+C private fee-for-service plans, as discussed below, M+C organizations offering such plans will be required to make the information described in § 422.202(a)(1) available to providers treating enrollees of the plan.

Section 1852(j) requires the provision of written notice of the participation rules. We are requiring in § 422.202 that any material changes in rules must be provided in writing in advance of implementation. Such advance communication would enable health care professionals to evaluate their continued participation prior to instituting a formal appeal process regarding any rules they believe are adverse. This benefits M+C organizations and providers in allowing the health care professional to judge what is adverse as this can vary among

individual health care professionals; what is adverse to one physician or health care professional may not be adverse to another.

2. Consultation (§ 422.202(b))

Consistent with section 1852(j)(2), § 422.202(b) requires an M+C organization to consult with physicians or relevant health care professionals who have entered into participation agreements/contracts with the organization regarding the organization's medical policy, quality and medical management procedures. Pursuant to our authority in section 1856(b)(1) to establish standards under the M+C program, in addition to requiring consultation on any aspect of clinical policy, we have included three specific standards relating to the development of practice guidelines—(1) practice guidelines and utilization management guidelines must be based on reasonable medical evidence or consensus of relevant practitioners, developed in consultation with participating practitioners, and reviewed and updated periodically; (2) the guidelines must be communicated to practitioners and, as appropriate, enrollees; and (3) decision making in utilization management, enrollee education, interpretation of covered benefits, and other areas to which the guidelines are applicable must be consistent with the guidelines. These three standards are taken from QISMC discussed in section II.D. of this preamble. These national standards also are consistent with the NAIC model act and language adopted for state laws regarding managed care. We believe these standards ensure that practitioners are fully consulted in all aspects of the use of practice guidelines from development to application.

3. Treatment of Subcontracted Networks (§ 422.202 (c))

In today's business environment, managed care organizations delegate not only the provision of services to subcontracted networks, but also a variety of policy making and implementation responsibilities. Each health care professional is an integral part of the organization's health care delivery system, whether he contracts directly with the organization or through an intermediary entity, such as an Independent Practice Association (IPA). Therefore, under our authority in section 1856(b)(1) to establish M+C standards, in § 422.202(c) we require provider protections not only for direct contracting physicians and health care professionals but also for all subcontracted arrangements. Extension of the BBA provisions to subcontracts means that providers within subnetworks (e.g. an IPA) receive the rules of participation, written notices, and have an opportunity to appeal. Thus, health care professionals within the subcontracted groups should be included in the procedures established for participation appeals and in the formulation of medical policy for the organization. In cases where subnetworks maintain most of the medical records for the Medicare beneficiaries they serve, it is essential that the formulation of policy includes all of the resources that contribute to fair and equitable treatment for beneficiaries. We also believe that subnetworks should have the ability to grieve or appeal decisions for the providers within their subnetworks.

4. Provider Credentialing and Provider Rights (§ 422.204)

Section 422.204(a), ''Basic Requirements,'' states that the M+C organization must have a system for credentialing physicians and other health care professionals. The M+C organization must ensure that providers meet applicable State and Federal requirements. Basic benefits must be provided through, or payments must be made to, providers that meet applicable requirements of title XVIII and part A of title XI of the Act. Also, in the case of providers meeting the definition of ''provider of services'' in section 1861(u), basic benefits may only be provided through such providers if they have a provider agreement with HCFA permitting them to provide services under original Medicare. An M+C organization may not employ or contract with providers excluded from participation in Medicare. M+C organizations, at a minimum, should check the OIG website at http://www.dhhs.gov/progorg/oig for the listing of excluded providers and entities. These requirements are promulgated pursuant to our authority under section 1856(b)(1) to establish M+C standards by regulation, and are based on (1) the requirement in section 1852(a)(1) of the Act that Medicare covered services be furnished through Medicare qualified providers, (2) existing requirements in § 417.416, and (3) detailed standards developed under QISMC, discussed in section D. above.

Section 422.204(b), ''Discrimination Prohibited,'' prohibits M+C organizations from discriminating with respect to provider participation, provider reimbursement, or provider indemnification to any provider acting within the scope of his license or certification under applicable State law, solely on the basis of such license or certification. These requirements are based on section 1852(b)(2). This does not prohibit plans from including providers only to the extent necessary to meet the needs of the plan's enrollees, ensure quality and control costs, and does not prohibit an organization from reimbursing different specialty providers differing fees for their services. It is however, the responsibility of the organization to adopt policies related to participation, reimbursement, and indemnification based on reasonable criteria. Organizations may want to consider such measures as health outcomes, satisfaction surveys, market saturation of the provider type or other legitimate reasons.

Under § 422.204(c), ''Denial, suspension, or termination of a contract,'' organizations offering coordinated care or network MSA plans are required to provide information on their plan participation criteria and an appeals process for participation decisions, including decisions involving denial, suspension or termination of contracts. We have incorporated the timeframes for contract termination notification between the M+C organization and its providers contained within the NAIC model act. As discussed in section C. above, we have incorporated similar timeframes for notice to enrollees about changes in the provider network, including changes that result from a termination covered under § 422.204(c).

The notice and appeals requirements in this part are based on the requirement in section 1852(j)(1)(C), requiring a process for appealing adverse participation decisions, and, as noted above, on the NAIC model act, and our authority under section 1856(b)(1) to establish standards under Part C.

5. Interference With Health Care Professionals' Advice to Enrollees Prohibited (§ 422.206)

Section 422.206 (a) incorporates the requirements set forth in section 1852(j)(3)(A). This section prohibits an M+C organization from interfering with the advice of a health care professional to an enrollee who is his or her patient. Thus the health professional may act within his or her scope of practice in advising the enrollee about their health status, all relevant medical or treatment options available regardless of whether care or treatment is provided under the plan. For purposes of § 422.206, the term health care professional includes those listed in section 1852(j)(3)(D) of the Act. Pursuant to our authority in section 1852(b)(1) to establish standards

under the M+C program, § 422.206(a) includes standards from the Consumer Bill of Rights that further delineate the types and mode of communication between patients and health care providers regarding health care treatment options within which interference is prohibited. While the scope of this section governs communication regarding care or treatment advice, we recognize that patients seek advice from physicians regarding insurance coverage choices as well as treatment option choices. Physicians can disclose their participation in M+C organizations, however, we are concerned about any inappropriate steerage based on knowledge of a beneficiary's health status or the physician's financial interest. Program instructions will be issued as HCFA continues to clarify policy in the area of provider marketing and the role of physicians and other health care professionals in disseminating M+C information to beneficiaries.

6. Conscience Protection (§ 422.206)

Section 422.206(b) incorporates the requirements of section 1852(j)(3)(B). The regulations state that the prohibition against interference with the content of advice a health care provider gives to enrollees regarding medical treatment should not be construed as requiring counseling by a professional or a referral to a service by that professional, if there is an objection based on moral or religious grounds, and the M+C organization fulfills certain notification requirements to prospective and current enrollees. The regulation incorporates the notification process and time frames included in the law and clarifies that the plan must also notify HCFA at the time of application and within 10 days of submitting its ACR proposal. With respect to current enrollees, the organization is eligible for the exception to the rule in § 422.206(a)(1) if it provides notice within 90 days after adopting the policy at issue; however, under § 422.111(d), notice of such a change must be provided in advance.

7. Physician Incentive Plans (§§ 422.208 and 422.210)

Consistent with section 1852(j)(4), regulations at §§ 422.208 and 422.210 outline the limitations on the operation of physician incentive plans. The provisions in this section are the same as those previously included in § 417.479 with some reduction in the amount of data that must be disclosed by the organization. HCFA has determined that the capitated data is no longer required because other sources of data, such as encounter data required by the Act and the National Data Reporting Requirements (NDRR) are available. The provisions are consistent with the provisions under section 1852(j)(4) which prohibit specific payments as a disincentive to provide services to an individual enrollee and which place limits on the transfer of substantial financial risk for referral services to physicians or physician groups contracting with the M+C organization. The provisions in these sections apply to all coordinated care and network MSA plans. M+C private fee-for-service plans are prohibited from having a physician incentive plan because they may not place their providers at financial risk. The physician incentive plans regulations require that M+C organizations conduct customer satisfaction surveys of both enrollees and disenrollees if any physician or physician group in an M+C organization's network is placed at substantial risk for referral services as defined in § 422.208. (Please note that there are at least two other uses of the term ''substantial financial risk'' contained in legislation or regulation. Specifically, section 216 of the Health Insurance Portability and Accountability Act of 1996 addressing safe harbors from the anti-kickback statute and the determination of substantial financial risk related to PSOs (63 FR 18124, April 14, 1998)) M+C organizations may satisfy their requirement for enrollee surveys either by their mandated inclusion in HCFA's national administration of the Consumer Assessments of Health Plans Study (CAHPS) or, if the organization is excluded from CAHPS due to not having contracted with us for at least one year, by conducting their own surveys.

8. Limitation on Provider Indemnification (§ 422.212)

Section 422.212 prohibits an M+C organization from having a provider, or group of providers, indemnify the organization against any liability arising from the organization's denial of medically necessary care. This prohibition is a very narrow exception for a civil action brought by, or on behalf of, an enrollee where the damage is due to a determination by the M+C organization to deny medically necessary care. The regulation includes the statutory language from section 1852(j)(5) without elaboration.

9. Special Rules for Services Provided by Noncontract Providers (§ 422.214)

Consistent with section 1852(k) and section 4002(e), the regulations in § 422.214 require any health care provider that does not have a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C coordinated care plan to accept as payment in full, the amounts that could have been collected if the beneficiary were enrolled in original Medicare. An M+C organization (other than an M+C MSA plan) satisfies its liability for Medicare covered services if the provider receives the total amount that would have been received if the beneficiary were enrolled in original Medicare. This amount equals the total of Medicare's payment (including any applicable deductible and coinsurance amounts) and any balance billing amount that would have been allowed by original Medicare. In the case of a participating physician or supplier, this amount would equal the Medicare fee schedule amount for the service. For a nonparticipating physician, this amount would equal 115 percent of the fee schedule amount for nonparticipating physicians (which is 95 percent of the fee schedule amount applicable to participating physicians). Of these amounts, the provider could collect from the M+C plan enrollee the cost sharing amount required under the M+C plan, as approved by HCFA under subpart G of part 422 and the remainder from the M+C organization.

Section 1866(a)(1)(O) places a limitation on what a provider of services (as defined in section 1861(u)) must accept as payment in full for services furnished to an M+C plan enrollee. The limit is applicable to those institutional type providers of service that do not have in effect a contract with the M+C organization establishing payment amounts for services furnished to an enrollee. The limitation equals the amount that would have been payable for a beneficiary enrolled in original Medicare less any payments that could be collected directly from Medicare representing graduate medical education (both direct and indirect).

10. Special Rules for M+C Private Fee-for-Service Plans

Special rules for M+C private fee-for-service plans are discussed in section IV of this preamble.

11. Exclusion of Services Furnished Under a Private Contract (§ 422.220)

Section 422.220 prohibits an M+C organization offering an M+C plan from paying for services furnished to an

enrollee by a physician or other health care professional who has signed a private contract as described in section 1802(b). Section 4507 of the BBA specifies that nothing in title XVIII of the Act shall prohibit a physician or practitioner from privately contracting with a beneficiary to furnish services for which no claim shall be submitted to Medicare and no Medicare payment shall be made directly or indirectly or by any organization paid by Medicare where the physician or practitioner has opted out of Medicare for 2 years. Therefore, no payment may be made by an M+C organization for services furnished to Medicare enrollees by a physician or practitioner who opts out of Medicare where he or she has signed a private contract with an enrollee. There is one exception: the physician or practitioner who has opted out of Medicare may not ask a beneficiary who requires emergency or urgent care to sign a private contract. Therefore, where a physician or practitioner who has opted out of Medicare provides emergency or urgent care to an enrollee of an M+C organization, the organization must pay for the emergency or urgent care the enrollee required. For purposes of this provision, we consider ''urgent care'' to mean urgently needed services as defined in § 422.2.

12. M+C Plans and the Physician Referral Prohibition

One other item that relates to M+C organizations but is not contained within the part 422 regulations is the physician referral prohibition.

a. *The prepaid health plan exception:* Under section 1877, if a physician or a member of a physician's immediate family has a financial relationship with a health care entity (through an ownership interest or a compensation relationship), the physician may not refer Medicare patients to that entity for any of 11 designated health services, unless an exception applies. Under an exception in section 1877(b)(3), the prohibition on referrals does not apply to services furnished by certain prepaid health plans. To qualify for the exception, the services must be furnished by one of the following organizations to its enrollees:

- Organizations with a contract under section 1876, which authorizes us to enter into contracts with HMOs and competitive medical plans (CMPs) to furnish covered items and services on a risk-sharing or reasonable cost basis.
- Organizations with health care prepayment plans, as described in section 1833(a)(1)(A), which authorizes payment for Medicare Part B services to prepaid health plans on a reasonable cost basis.
- Organizations receiving payments on a prepaid basis under a demonstration project under section 402(a) of the Social Security Amendments of 1967 or section 222(a) of the Social Security Amendments of 1972.
- Qualified health maintenance organizations, within the meaning of section 1310(d) of the Public Health Service Act.

As discussed in section I. of this preamble, beginning in January 1999, the new M+C program replaces the HMO and CMP risk contracting program provided for in section 1876.

In enacting the BBA, Congress failed to revise section 1877(b)(3) to except the services furnished under M+C coordinated care plans. We believe that this must have been an oversight, since Congress expressed no intention in the legislative history for the BBA of subjecting existing managed care entities to the self-referral law. In addition, subjecting physicians who have an ownership interest in an M+C organization offering a coordinated care plan in which the physicians participate, to the self-referral rules would be contradictory to Congress' purposes in establishing PSOs as coordinated care plans. PSOs are defined in the BBA provisions as entities that must be organized and operated by a provider (which may be a physician) or a group of affiliated health care providers (which may include physicians). These providers must share a substantial financial risk for the provision of items and services and have at least a majority financial interest in the entity. The self-referral provisions, on the other hand, are specifically designed to discourage physician ownership of entities that provide a broad range of services to Medicare beneficiaries.

b. *No risk of program or patient abuse exception—Coordinated Care Plans:* Although there is no statutory exception for services furnished under coordinated care plans, section 1877(b)(4) allows us to create an exception to the referral prohibition for a financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse. An example of program abuse is Medicare payment for unnecessary services. We will pay M+C organizations for enrollees in coordinated care plans on a capitated basis and beneficiaries will be responsible for premiums and cost sharing. Section 1854 limits HCFA's capitation amount and the total amount of beneficiary premiums and cost-sharing. Because M+C organizations offering coordinated care plans will not be paid for each additional service they provide, we believe that there is no risk of over-utilization of services. Because HCFA's capitation amount and the total amount of beneficiary premiums and cost sharing is limited, we believe that there is no risk of program or patient abuse.

Therefore, we are excluding from the physician referral prohibition services furnished under a coordinated care plan to an enrollee. This exception applies in all cases in which a physician has an ownership interest in or a compensation relationship with the M+C organization offering the coordinated care plan. We are making a change in the regulation text at § 411.355(c)(5).

c. *No risk of program or patient abuse exception—M+C MSA Plans:* M+C organizations offering an M+C MSA plan are paid a fixed capitation amount for beneficiaries enrolled in the plan, and section 1853(a) limits HCFA's capitation amount and section 1859(a)(3)(A) limits the amount that M+C organizations under M+C MSA plans will pay entities for furnishing covered services. Section 1859(a)(3)(B) limits the annual deductible amount. However, the Act does not similarly limit the amount that a beneficiary will have to pay as premiums and costsharing; that is, there is no limit on beneficiary balance billing by the entities that furnish health care services. *See* section IV. below. Thus, although there is no risk of program abuse, there is a risk of patient abuse. Therefore, we are not excluding from the physician referral prohibition services furnished under an M+C MSA.

d. *No risk of program or patient abuse exception—Private fee-for-service plans:* Section 1853(a) also limits HCFA's capitation amount to be paid to M+C organizations under private fee-for-service-plans. Because there will not be excessive payments by the Medicare program, there is no risk of program abuse. However, section 1859(b)(2)(A) provides that the plans will pay an individual or entity furnishing services on a fee-for-service basis. Since beneficiaries are responsible for coinsurance amounts, copayments, and balance billing amounts under private fee-for-service plans (*see* section IV. of this preamble), beneficiaries are subject to added out-of-pocket liability if physicians providing services under a fee-for-service plan order additional unneeded services in order to obtain additional fee-for-service payments from the M+C organization offering the private fee-for-service plan. Thus,

although there is no risk of program abuse in this case, excessive Medicare payment, there is a risk of patient abuse. Therefore, we are not excluding from the physician referral prohibition services furnished under a private fee-for-service plan.

F. Payments to M+C Organizations

1. General Provisions (§ 422.250)

Subpart F of part 422 sets forth rules that govern Medicare payment to M+C organizations, including the methodology used to calculate M+C capitation rates. These rules also apply for 1998 under section 1876 risk contracts.

Payments and Adjustments: We provide in § 422.250(a)(1) that, with the exception of payments under M+C MSA plans and payments for ESRD enrollees in all other plans, which we discuss below, we will pay M+C organizations for each enrollee in an M+C plan they offer, a monthly payment that is equal to 1/12th of the county-wide (or, in the case of ESRD enrollees, 1/12th of the State rate) ''capitation rate'' under § 422.252 that applies for the county in which the enrollee lives, adjusted by demographic factors applicable to that enrollee. Effective January 1, 2000, however, section 1853(a)(3)(C) directs us to implement a risk adjustment methodology that accounts for variation in per capita cost based on health status and demographic factors. Implementation of health status risk adjusters has implications for M+C plan data submissions, and we discuss this issue further below.

In addition to health status and demographic risk adjustments, we make an adjustment, under § 422.250(a)(2)(i)(A), to the payment rate for M+C enrollees with end-stage renal disease (ESRD). Under § 422.250(a)(2)(i)(B), we make an adjustment that is the equivalent to a 50 cent reduction for each renal dialysis treatment that we will use to help pay for the ESRD network program in the same manner as other reductions are used in original Medicare. Finally, under § 422.250(b), we provide for making retroactive adjustments to the aggregate monthly payment to an M+C organization to reflect any difference between the actual number of enrollees and the number upon which we had based the organization's advance monthly payment.

Under § 422.250(a)(2)(ii) for M+C MSA plan enrollees, we make a monthly payment to the M+C organization as described above less the amount (if any) identified in § 422.262(c)(1)(ii) to be deposited in the M+C MSA. In addition, we deposit in the M+C MSA the lump sum amounts (if any) determined in accordance with § 422.262(c). See section III. below for a more complete discussion of payments under M+C MSA plans.

In § 422.250(a)(2)(iii), we provide for adjustments to be made to payments under RFB plans (which are limited to members of a religious and fraternal benefit plan) to ensure that the payment level is appropriate for the actuarial characteristics and experience of [RFB plan] enrollees.

Payment Areas: In § 422.250(c)(1), we reflect the general rule, under section 1853(d) of the Act, that the M+C payment area is a county or equivalent area specified by HCFA. Under § 422.250(c)(2), in the case of beneficiaries with ESRD, the payment area is the State or equivalent area we specify. Additionally, in a significant change to payment area policy from the section 1876 program, section 1853(d)(3) permits Governors of States to request that we approve alternative geographic areas for payment rates. These alternatives are either a single State-wide M+C payment area or a metropolitan-based system in which all nonmetropolitan areas within the State constitute a single payment area, and any of the following constitutes a separate M+C payment area:

- All portions of each single metropolitan statistical area within the State.
- All portions of each primary metropolitan statistical area within each consolidated metropolitan statistical area within the State.
- A consolidation of noncontiguous counties.

Section 1853(d)(3) directs us to approve a Governor's request; however, this section of the Act also directs us to subject these requests to a budget neutrality requirement, and any payment for alternative geographic areas cannot exceed the aggregate payments for that State absent the adjustment. Additionally, the Governor's request must be submitted to us no later than February 1 of the year preceding the contract year. This provision is implemented in § 422.250(e).

2. Annual Capitation Rates (§ 422.252)

Among the more significant payment changes in section 1853 is the incremental separation of capitated Medicare payments from local fee-for-service rates. Previously, Medicare had paid risk contractors according to the Adjusted Average Per Capita Cost (AAPCC) payment methodology. The AAPCC was based on Medicare fee-for-service expenditures by county and was used to pay risk contractors through December 31, 1997. These fee-for-service expenditures were adjusted for demographic factors (that is, age; sex; institutional, welfare, and employment status).

The AAPCC had been legitimately criticized for its wide range of payment rates among geographic regions—in some cases it varied by over 20 percent between adjacent counties. It was also criticized for its poor risk adjustment capabilities and inappropriate provision of graduate medical education funds to some Medicare risk plans. Moreover, the AAPCC was criticized for setting erratic annual payment updates, which often made it difficult for contracting health plans to engage in long-term business planning. The BBA introduces a new payment methodology that addresses these and other concerns, and we discuss them in detail below.

''Greater of'' Payment Rate: Since January 1, 1998, Medicare capitation rates paid to section 1876 risk contractors for each calendar year have been the greater of a blended capitation rate, a minimum amount rate, or a minimum percentage increase. This same methodology will apply to payments under M+C contracts.

- The blended capitation rate is a blend of the area-specific (local) rate and the national rate, with the latter adjusted for input prices. The blended capitation rate is then adjusted by a budget neutrality factor.
- The minimum amount rate will equal $367 per month per enrollee in 1998 for all areas in the 50 States and the District of Columbia. Outside the 50 States and the District of Columbia, the rate is not to exceed 150 percent of the 1997 AAPCC for those areas. The minimum amount rate will be adjusted each year using the update factors described below. (On an individual basis, our monthly payment may be more or less than the minimum amount due to the demographic or other risk factors applicable to that individual used to adjust the minimum amount rate.)
- The minimum percentage increase is 2 percent. The minimum percentage increase rate for 1998 is 102 percent of the 1997 AAPCC. Thereafter, it is 102 percent of the prior year's rate.

3. Calculation and Adjustment Factors (§ 422.254)

Blend of Area-Specific and National Percentages: The 1997 AAPCC capitation rates serve as the base for both the area-specific rates in the blend and the minimum percentage increase rates. Section 1853(c)(2) stipulates that the blended area-specific/national rate

(discussed further below) will be implemented over a 6 year transition period from 1998 through 2002 according to the following schedule:

- 90 percent area-specific/10 percent national in 1998
- 82 percent area-specific/18 percent national in 1999
- 74 percent area-specific/26 percent national in 2000
- 66 percent area-specific/34 percent national in 2001
- 58 percent area-specific/42 percent national in 2002
- 50 percent area-specific/50 percent national in 2003 and thereafter.

Section 1853(c)(6) also provides for a ''national per capita M+C growth percentage.'' Each year, from 1998 through 2002, this national growth percentage is applied to the national and local components of the blended rate and to the floor rate (discussed below). The national per capita growth percentage is HCFA's projection of per capita expenses, reduced by the following amounts established in section 1853(c)(6): 0.8 percentage points in 1998 and 0.5 percentage points each year from 1999 through 2002. After 2002, the reduction amount is zero. This provision is implemented in § 422.254(d).

As indicated above, the blended rates are adjusted by a budget neutrality factor. Section 1853(c)(5) provides for a ''budget neutrality'' adjustment to the blended capitation rate under § 422.252(a), designed to ensure that the aggregate amount paid under the M+C payment methodology equals the amount that would have been paid if payments were based entirely on area-specific rates (as they were under section 1876(a)). The statute requires that this budget neutrality adjustment apply only to the blended capitation rate under § 422.252(a), rather than to the final capitation rate under § 422.252. Since the capitation rate is based upon the *highest* of the blended capitation rate, the minimum payment, and the prior year's payment plus 2 percent, the budget neutrality adjustment cannot produce any further savings once the blended capitation rate is reduced to the point where it is lower than the other two amounts in every county. This is what happened for 1998 and 1999. For these years, the budget neutrality adjustment reduced the blended rate to the point where no county's payment rate is based upon the blended rate, since one of the two other rates is higher in every county. Yet, even with this reduction, the goal of the budget neutrality provision in section 1853(c)(5) was not met for 1998 and 1999. We are considering seeking a statutory change to address this problem.

Area-Specific Component of the Blended Capitation Rate: Above we discussed the relationship between area-specific and national rates and how they are intended to develop into a 50/50 balance by the year 2003. Here we discuss features of the area-specific (local) rate and, directly below, features of the national rate.

In 1998, the base for the area-specific rate is the 1997 AAPCC, adjusted for 20 percent of the indirect medical education/direct graduate medical education (GME) carve-out. This is a significant change to payment policy under section 1876 Medicare ''risk'' contracts. In accordance with section 1853(c)(3)(B), under § 422.254(e)(2), we will remove all graduate medical education payments in the base rate between 1998 and 2002 on the following schedule: 20 percent in 1998; 40 percent in 1999; 60 percent in 2000; 80 percent in 2001; and 100 percent in 2002 and thereafter. These GME funds will be removed from the area-specific portion of the blended rate. Since the national portion of the blend is computed based on the adjusted local rates, it also reflects removal of these GME funds. Teaching hospitals will be paid directly for the GME costs associated with Medicare managed care enrollees under § 412.322.

Additionally, pursuant to section 1853(c)(3)(C)(ii), in § 422.254(e)(3), to the extent we estimate that the 1997 per capita base rate reflects payments to State hospitals under section 1814(b)(3), we will make appropriate adjustments to the M+C payment rate. Payments are made to hospitals located in Maryland under this provision.

Finally, pursuant to section 1853(c)(3)(D), in § 422.254(e)(4), we provide that HCFA may substitute a rate for the 1997 capitation rate a rate that is more representative of the costs of the enrollees in the area if the 1997 rate varied by more than 20 percent from the 1996 rate.

National Component of the Blended Capitation Rate: The national component of the blended capitation rate has two major features: (1) the national standardized annual capitation rate; and (2) the national input-price-adjusted capitation rate.

The national standardized annual capitation rate is a weighted average of all area-specific rates adjusted for risk factor weights used to calculate payments as though all eligible individuals were members of an M+C plan. The calculation for the national standardized annual capitation rate is described at § 422.254(f).

The input-price-adjusted annual national capitation rate is adjusted for geographic variation in the prices of goods and services used to produce medical services and is the sum of the products of three amounts:

- The national standardized annual capitation rate for the year, which consists of the weighted average of all area-specific capitation rates.
- The proportion of the rate that is attributable to each type of service.
- An index that reflects (for that year and that type of service) the relative input price of services in the area, as compared to the national average input price for these services.

The input-price-adjusted annual national capitation rate is described in § 422.254(g).

4. Adjustments to Capitation Rates and Aggregate Payments (§ 422.256)

Beginning with 1999 payment rates, we will adjust all area-specific and national capitation rates (and beginning with the 2000 payment rates, the minimum amount rate) for the previous year to reflect any differences between the projected national per capita growth percentages and the current estimates of those percentages.

We will also adjust for national coverage determinations (NCD) that were significant cost as defined in § 422.109 and defined above. An NCD is a national policy statement regarding the coverage status of a specified service that we make under administrative authority and publish in the **Federal Register** as a notice of HCFA Ruling. (The term does not include coverage changes mandated by statute.)

If we determine that the cost of furnishing a service subject to an NCD is ''significant,'' we will adjust capitation rates for the next calendar year to take into account the cost of that service. Until the new capitation rates are in effect, the M+C organization would be paid through original Medicare for the provision of such services.

Risk Adjustment: Section 1853(a)(3) requires us to develop and submit to the Congress, by March 1, 1999, a report on a proposed method of risk adjustment of M+C payment rates. We are also required to implement a risk-adjustment methodology for payment periods beginning on or after January 1, 2000. We provide for such risk adjustment in § 422.256(d). Under the previous payment methodology, the AAPCC, we used a demographic risk adjuster that has been criticized as an inadequate predictor of health care costs.

Nonetheless, until the new risk adjustment methodology is implemented in 2000, we will be using the same demographic adjusters used under the AAPCC method to make demographic adjustments under § 422.256(c) to the capitation rate determined under § 422.252. Section 1853(a)(3)(C) specifically directs HCFA to implement health-status based risk adjusters, as well as ''other demographic factors.'' Section 1853(a)(3)(D) requires that, with the exception of enrollees in M+C RFB plans, the same risk adjustment methodology be used for all enrollees in M+C plans, regardless of plan type. The implementation of health-status based risk adjusters has major implications for M+C organizations' data requirements, as discussed directly below.

5. Encounter Data (§ 422.257)

Section 1853(a)(3)(B) addresses the collection of encounter data from M+C organizations needed to implement the risk adjustment methodology. The Act requires that the collection of inpatient hospital data for discharges beginning on or after July 1, 1997 and allows the collection of other data no earlier than July 1, 1998. The statutory language is tied to the creation of risk-adjusted payment rates, as defined at § 422.256(c) and (d) of this rule. Requirements concerning collection of encounter data apply to M+C organizations with respect to all their M+C plans, including and private fee-for-service plans.

There are two different ways encounter data are used for risk-adjustment purposes. To calculate payment rates, encounter data are necessary to tie payment to expected patient resource use using diagnosis codes. The initial risk-adjusted payment will be based on inpatient hospital encounter data. However, use of an inpatient-based system in the long run has two major weaknesses: (1) It provides M+C organizations with an incentive to hospitalize their enrollees in order to receive additional payment; and (2) a risk-adjustor system based only on inpatient hospital diagnosis codes will not allow more accurate payment for the chronically-ill-but-not-hospitalized. For both of these reasons, we have developed a more comprehensive risk-adjustment methodology that uses diagnosis data from physician services and hospital outpatient department encounters. In addition, physician services data include data from limited license practitioners, such as clinical psychologists and nurse midwives who provide services independently, but do not include nonprofessional services ordered by physicians as a result of the initial physician services furnished, such as laboratory services and durable medical equipment.

Encounter data are also necessary to ''recalibrate'' any risk-adjusted payment model. Recalibration is necessary to adjust the payment models for improved coding. For example, upcoding may occur if plans improve coding of beneficiary diagnoses and, as a result, the average use of resources for enrollees in a particular category may be less than when the relative payment rates were determined. When this happens, the average actual expenditures per enrollee for these diagnoses are less than the average expenditures used to assign the original payment weights. The result is overpayment for some diagnoses in the risk adjustment model. To account for possible coding changes, all risk adjustor payment model diagnosis weights would be recalculated, or ''recalibrated'' based on encounter data gathered after implementation of risk adjustment. A preferred method for full recalibration requires that all services provided to each M+C plan enrollee be priced and the total cost of care determined for each enrollee. This approach would require that organizations submit encounter data for all services provided to each enrollee. An alternative approach would require the organizations to submit to HCFA the cost of providing medical care for each Medicare enrollee, but organizations might oppose such a requirement as too intrusive.

While the purpose of collecting the encounter data will be to calculate risk-adjusted payments, there are a wide variety of other uses of whatever data we collect. Quality improvement targets can be identified using encounter data. Our ability to monitor the care received by M+C enrollees through targeted special studies (such as an examination of post-acute care utilization patterns) will be greatly enhanced by the availability of encounter data. Encounter data will also be useful for program integrity functions, both by providing additional utilization norms for original Medicare billing and by providing additional information regarding M+C organizations' behavior.

Timing of Encounter Data Collection: The first issue to address with regard to data collection is the ability of the organizations to generate the necessary data and to ensure accurate transmission. While some organizations will be able to transmit encounter data quickly and with little difficulty, others will be further behind in their internal information systems development. To the extent that organizations have capitated arrangements with their providers, they may not currently require encounter-type data from those providers. The ability to generate encounter data may well vary by type of service provided as well as by type of organization submitting the data. All organizations will have to conform to the HIPAA information system standards regarding encounter data formats by 24 months (36 months for small organizations) after the effective date of the final rule (currently estimated to be published in the fall of 1998), so the main issues with regard to the organizations should be transition issues rather than long run implementation issues.

HCFA has issued instructions delineating a specific timetable for M+C organizations to submit inpatient hospital data. M+C organizations will be required to select a fiscal intermediary designated by HCFA to transmit data.

Given any start date, comprehensive risk-adjusted payments will be made about 3 years after the year of the initial collection of outpatient hospital and physician encounter data. Similarly, recalibration of the risk-adjusted payments to reflect managed care practice patterns could occur about 3 years after the complete data are collected. In order to minimize the period for which payments are determined based on inpatient hospital data only, we will provide advance notice to M+C organizations to collect and submit physician, outpatient hospital, SNF, and HHA data beginning no earlier than October 1, 1999; and all other data HCFA deems necessary beginning no earlier than October 1, 2000.

Because M+C organization payments will depend on the data transmitted and because M+C organizations are the entities with which HCFA contracts, we will hold the M+C organization responsible for transmission of the data. If the M+C organization is held responsible, it follows that they should transmit the data directly, rather than monitoring the transmission by their providers. We will allow organizations to hire third party data transmitters, but the M+C organization will be responsible for the accuracy and completeness of the data transmitted.

Data Format: The format of the data we will require will be identical to the data we require of original Medicare providers of similar services, because pricing of the data using original Medicare's methods is necessary for recalibration. The data will be processed using designated HCFA contractors. Providers are familiar with the HCFA

1500 (or its electronic equivalent) and the electronic UB–92 (or other electronic equivalent) through their original Medicare billings. In addition, organizations will have mechanisms in place to receive UB–92 data from hospitals and send it to fiscal intermediaries by July 1, 1998, because of the requirements for submission of inpatient encounter data. It would clearly be beneficial to all parties to use the UB–92 and this transmission format for any other required data that is currently submitted on the UB–92 in original Medicare. There are no current organization-to-carrier links for data HCFA currently processes on the electronic version of the HCFA 1500. From the provider, contractor, and HCFA point of view, it is clear that use of the electronic version of the HCFA 1500 would minimize any data collection burden.

Data Accuracy: Audit of the data will be necessary to ensure accuracy; any audit efforts will include medical record review for a portion of the submitted data. Statistical analysis (for example, examination of hospitalization rates for various organizations and inquiry into outliers) will be combined with traditional audit methods in order to maximize our examination of the data while managing the amount of contractor resources used for audit.

6. Announcement of Annual Capitation Rates and Methodology Changes (§ 422.258)

Previously, under section 1876, we were required to announce Medicare risk contractor payment rates by the first week in September, no later than 45 days after publishing for comment our mid-July announcement of payment methodology changes. This schedule was designed to allow HMOs and CMPs time to consider the coming year's payment rates, decide about their continued participation in the Medicare program, calculate their Adjusted Community Rate (ACR) proposal, and, finally, afford us the time to approve or disapprove the ACR proposal prior to the January 1 contract effective date.

Under section 1853(b)(1), starting in 1998, we must announce rates by March 1 of the year prior to the year the rates apply. We must include in this announcement a description of the risk and other factors and explain the methodology in sufficient detail to enable M+C organizations to compute monthly adjusted capitation rates for individuals in each of their payment areas.

The March 1 announcement will ensure that subsequent events can occur to meet the November annual coordinated election period stipulated in section 1851(e)(3). As under prior law, 45 days prior to announcing payment rates on March 1, section 1853(b)(2) requires us to provide notice of changes in the methodology and assumptions used in the previous year.

7. Special Rules for Beneficiaries Enrolled in M+C MSA Plans (§ 422.262)

The BBA establishes special rules for beneficiaries enrolled in M+C MSA plans, and we discuss them in detail under section III. below.

8. Special Rules for Coverage That Begins or Ends During an Inpatient Hospital Stay (§ 422.264)

The BBA contains special payment rules for situations where an M+C enrollee's coverage begins or ends while the Medicare beneficiary is a hospital inpatient. Section 1853(g) provides that, where a beneficiary is receiving inpatient hospital services from a hospital covered under original Medicare's prospective payment system (PPS) or another M+C organization on the effective date his or her M+C election of a new M+C plan, payment for inpatient services (up until the date of discharge) would continue to be the responsibility of the original Medicare program or previous M+C organization. The M+C organization offering the newly elected M+C plan would not be responsible for inpatient hospital service payment until the date of discharge, and original Medicare or the previous M+C organization would pay the full amount for that beneficiary for that inpatient episode, even if it extends beyond the effective date of a beneficiary's M+C election.

In the case of a beneficiary's M+C plan election ending while he or she is a hospital inpatient, the M+C organization remains responsible for payment for inpatient hospital services furnished by a hospital after expiration of enrollment up until the date of discharge. Payment for these services would not be made under Medicare's PPS system, and the responsible M+C organization would not receive any payment from us for the hospitalized individual during the period the individual was not enrolled.

9. Special Rules for Hospice Care (§ 422.266)

Section 1853(h) of the BBA contains special provisions for Medicare beneficiaries who elect hospice care concurrent with their enrollment in an M+C organization. Specifically, an M+C organization must inform each Medicare enrollee eligible to elect hospice care under section 1812(d)(1) about Medicare hospice programs within the M+C plan's service area. If it is common practice to refer patients to hospice areas outside the service area, the organization must inform the M+C enrollee of that as well. This information must be provided to beneficiaries in a manner that objectively presents all available hospice providers, including a statement of any ownership interest held by the M+C organization or a related entity. If the M+C organization has an ownership or other financial interest in one or more of the available hospice providers, M+C plan enrollees cannot be required to use that hospice provider.

BBA payment provisions for hospice care state that our monthly payment to the M+C organization will be reduced to an amount equal to the adjusted excess amount in the M+C plan's approved ACR. Beyond the adjusted excess amount, we pay through original Medicare for hospice care furnished to the M+C plan enrollee. We also pay through original Medicare (to the M+C organization), for other Medicare-covered services furnished to the hospice patient.

Unless the individual disenrolls from the M+C plan, an M+C enrollee electing hospice continues his or her enrollment in the plan and is entitled to receive through the plan any benefits, other than those that are the responsibility of the Medicare hospice.

10. Source of Payment (§ 422.268)

As under the section 1876 risk program, we will determine which proportion of payments to M+C organizations comes from the Hospital Insurance Trust Fund (Part A) and which proportion of payments comes from the Supplementary Medical Insurance Trust Fund (Part B). We determine these proportions based on the actuarial value of total benefits under both parts.

G. Premiums and Cost-Sharing

Subpart G of part 422 details provisions found in section 1854 for the M+C program. In this subpart we discuss how limits on M+C plan enrollee premiums and other cost sharing are established through the ACR approval process. The ACR process is applicable to all M+C plans except M+C MSA plans. M+C MSA plans are not required to submit an ACR, but other information must be submitted for HCFA's review (see discussion below). We discuss limitations that the process imposes on other cost-sharing that M+C organizations may impose on Medicare enrollees for the M+C plan they elect.

Note that there are a number of terms pertinent to the following discussion, and they are defined in § 422.302 of this rule. ACR and APR are terms that were used under section 1876 risk program. Section 1854(b) discusses the definition of the terms relating to beneficiary premiums. The term additional revenues is discussed in detail in section 5 below.

As under the section 1876 risk program, the ACR process under the BBA serves three important purposes. First, HCFA examines an M+C organization's ACR proposal for each M+C plan to determine whether Medicare payments in excess of the amount the organization would charge commercially for Medicare-covered benefits are passed on to beneficiaries in the form of added additional benefits. Second, we review ACR proposals to determine whether the structure of premiums, deductibles, copayment, and coinsurance charged to beneficiaries are within the limits established by law as required under section 1854(f)(1)(A). Third, benefit package information is reviewed to determine whether the benefit package is in compliance with the principles contained in subpart C.

We have taken into account that the M+C program is a significant departure from the section 1876 risk contracting program it replaces. Therefore, we are allowing a special period during which organizations will be able to add benefits (at no additional cost to the M+C plan enrollee) or lower premiums or cost-sharing mid-year. We also are providing for the submission of ACRs on a date other than May 1 if a contract will begin on a date other than January 1. The transition rules for this period are found in § 422.300(b). This special period will end on December 31, 2001.

1. Rules Governing Premiums (§ 422.304)

This section of the regulation implements provisions of the BBA relating to premiums paid by (or behalf of) beneficiaries. Each Medicare enrollee must be afforded the opportunity to pay the M+C plan premium on a monthly basis and, as under the section 1876 risk program, pursuant to Section 1128B(b) of the Act, the M+C organization may not provide for cash or other financial rebate as an inducement for enrollment (or for any other reason).

As discussed in above, section 1852(a)(1) requires an M+C organization to include in its M+C plan all services covered under original Medicare (except hospice care) that are available to Medicare beneficiaries in the area in which services are covered under the M+C plan. In addition, additional benefits must be provided to all enrollees electing the M+C plan (see section 1854(f)(1)). Section 1852(a)(3) allows an M+C organization to add supplemental benefits to the M+C plan either at the M+C organization's discretion (with our approval) or at the enrollee's election. For these benefits offered through a coordinated care plan, section 1854(e) does not allow the M+C organization in total, for the year, to impose a total average cost to the beneficiary, with an actuarial value greater than the actuarial value of original Medicare's deductibles and coinsurance for items and services covered by original Medicare plus the actuarial value approved through the ACR process for supplemental services. For M+C PFFS and M+C MSA plans, see discussion below.

Section 1854(c) provides that M+C basic and supplemental beneficiary premiums and M+C MSA premiums may not vary among individuals enrolled in the plan. This means that all enrollees in a given M+C plan must be charged the same premium amount for basic benefits and for any supplemental benefits the M+C organization may choose to offer. In the case of coordinated care plans, this uniform premium counts toward an overall limit on the actuarial value of beneficiary liability in section 1854(e) (discussed further below). Thus, in the case of coordinated care plans, the actuarial value of any cost-sharing imposed under the plan would also be uniform, since a uniform premium would be subtracted from a uniform overall limit to determine the amount that can be charged in cost-sharing.

We believe that section 1854(c) reflects congressional intent that all beneficiaries enrolled under a particular M+C plan pay the same amount. While cost-sharing amounts are not expressly mentioned, in the case of coordinated care plans, there is a uniform limit on the actuarial value of cost-sharing. Accordingly, pursuant to our authority in section 1856(b)(1) to establish M+C standards, we are providing in § 422.304(b) that M+C organizations may not vary the level of copayments, coinsurance, or deductibles charged for basic benefits or supplemental benefits among individuals enrolled in an M+C plan.

2. Submission of Proposed Premiums and Related Information (§ 422.306)

Section 1854(a) requires each M+C organization to submit no later than May 1 information about the M+C plan the organization wants to offer in the subsequent year. As under the Medicare section 1876 risk program, except in the case of M+C MSA plans, such information includes a complete description of the services included in the M+C plan, ACR and service area information, premium amounts, and descriptions of enrollee cost sharing. For M+C MSA plans, organizations have to submit the MSA premium that is used to determine the MSA deposit. No ACRs are required for M+C MSA plans. Pursuant to our authority in section 1856(b)(1), we have added a new requirement that M+C organizations also submit information on amounts collected in the previous contract period for basic benefits. We have done this to assure Medicare enrollees are not being charged cost-sharing that exceeds the limits in section 1854(e)(see § 422.308).

Section 422.306(a) reflects the requirement in section 1854(a)(1) that the information in paragraphs (b), (c), and (d) of § 422.306 be submitted by May 1 of the year prior to the year for which the information is submitted. This information is needed timely in order for HCFA to comply with the requirement in subpart B that comparative information on M+C plans be provided to Medicare enrollees. As noted above, during the transition period prior to 2002 provided for in § 422.300(b), M+C organizations may be permitted, at HCFA's discretion, to submit applications and ACR information on a flow basis and as discussed in section K below, under § 422.504(d) contracts could begin on a date other than January 1. In such a case, benefit package and pricing structures must be approved before the contract can take effect. Beginning with the 2002 calendar year, however, anyone wishing to offer an M+C plan in that year *must* submit an ACR by May 1 of the previous year (May 1, 2001 in the case of 2002).

If the information submitted is not complete, accurate, or timely, HCFA has the authority to impose sanctions under subpart O or may choose not to renew the contract.

We will review and approve all information submitted except for any amounts submitted by M+C MSA plans and premiums submitted by M+C private fee-for-service plans. Premiums and cost sharing will be reviewed in accordance with the rules established in § 422.310. Benefits offered under the M+C plan will reviewed in accordance with the rules established in Subpart C.

3. Limits on Premiums and Cost-Sharing Amounts (§ 422.308)

The rules in this section set the limits on the amount an M+C organization may charge a Medicare enrollee of an M+C plan. Section 1854(b) specifies that

the premium that a beneficiary is charged under an M+C plan other than an M+C MSA plan is the M+C monthly basic premium, plus any M+C supplemental premium. In the case of an M+C MSA plan, the beneficiary is charged only any M+C supplemental premium that may apply. The limits of Medicare enrollee liability are:

- For M+C basic benefits (Medicare covered services and additional benefits) offered by coordinated care plans: 12 times the basic monthly premium, plus the actuarial value of plan cost-sharing (copayments, coinsurance, and deductibles) for the year, cannot exceed the actuarial value of original Medicare's deductibles and coinsurance for the year or, if less, the amount authorized to be charged in the ACR (see § 422.310).
- For M+C basic benefits (Medicare covered services and additional benefits) offered by M+C private fee-for-service plans: the actuarial value of plan cost sharing (copayments, coinsurance, and deductibles) for the year, cannot exceed the actuarial value of original Medicare's deductibles and coinsurance for the year or, if less, the amount authorized to be charged in the ACR (see § 422.310).
- For supplemental benefits offered by a coordinated care plan: 12 times the M+C monthly supplemental premium plus the actuarial value of plan cost sharing (copayments, coinsurance, and deductibles) cannot exceed the ACR for such benefit or, if less, the amount authorized to be charged in the ACR (see § 422.310).

It is possible for an M+C organization to have M+C plan enrollees that are entitled to Medicare Part B benefits only. Section 1876(k)(2) specifies that existing Part B enrollees under section 1876 risk contracts on December 31, 1998 may remain as enrollees of the organization in accordance with regulations under section 1856(b)(1) if the organization enters into an M+C contract on January 1, 1999. Pursuant to sections 1876(k)(2) and 1856(b)(1), this final rule provides for such continued Part B-only enrollment, and § 422.308 provides that the limit on enrollee charges is the same as the limit that applies to other enrollees, except that the limit is based only on the actuarial value of cost sharing paid under Part B of original Medicare.

Also pursuant to our authority in sections 1876(k)(2) and 1856(b)(1), in § 422.308(a)(3), we impose a limit on the liability of Part B-only enrollees for an M+C organization's coverage of services that would be covered by Medicare Part A if the enrollee had Part A coverage. Specifically, we provide that the premium and cost sharing charged for such coverage may not exceed the lesser of what Medicare would pay an M+C plan in capitation for the services, plus the actuarial value of Medicare Part A deductibles and coinsurance, or the ACR for such services.

The above-described limits on enrollee liability apply to enrollee costs incurred for services furnished by noncontracting providers as well as providers that contract with the M+C organization offering the M+C plan in which the beneficiary is enrolled. In the case of contracting providers, limits on enrollee liability would generally be delineated in the contract between the provider and the M+C organization. Also, in the case of most coordinated care plans (for example, HMOs), it could be assumed that most nonemergency services will be obtained through contract providers.

Thus, to the extent an M+C coordinated care plan provides for different cost sharing in the case of noncontracting providers, it is not difficult to estimate the percentage of services that will be obtained at that level of cost sharing, when making the overall projection of the actuarial value of the cost sharing structure. In the case of M+C private fee-for-service plans, it is less clear to what extent noncontracting providers will be used, and the information on actual cost sharing from the prior year will be particularly valuable in assessing the accuracy of actuarial projections by the M+C organization. We note that in all cases, beneficiary liability is limited to the cost sharing provided for under the plan in the case of noncontract provider services. While sections 1852(k) and 1866(a)(1)(O) require noncontracting providers to accept as payment in full the amounts that they would be required to accept under original Medicare, balance billing to the beneficiary may be permitted under original Medicare but it is not permitted under the M+C plan in question. The M+C organization must hold beneficiaries harmless against any such balance billing. *See* section IV. below for a discussion of this issue in connection with M+C private fee-for-service plans and section III in connection with M+C MSA plans.

4. Incorrect Collections of Premiums and Other Cost Sharing (§ 422.309)

This section contains procedures to be used in situations where an M+C organization collects more than the amount that is allowed to be charged to the Medicare enrollee. These procedures were developed using the rules previously applied under section 1876 and promulgated under our authority in section 1856(b)(1) to establish standards under Part C.

Section 1857(d) requires that at least ⅓ of the M+C organizations be audited for, among other things, data used in the submitted ACR and all charges to the M+C plan enrollee for benefits covered under the M+C plan. These audits may reveal that the M+C organization has been overcharging the M+C plan enrollees. Section 422.309 requires the M+C organization to refund these over collections through an adjustment to current and future premiums allowed to be charged across all M+C plan enrollees.

We note that in addition to the above requirements for refunding amounts incorrectly collected, an M+C organization that collects amounts in excess of those permitted is subject to intermediate sanctions and civil money penalties under subpart O. *See* section 422.752(a)(2) and discussion below in section II. O. of the preamble. Refunding amounts improperly collected, at a minimum, would be a prerequisite to the lifting of such sanctions.

5. ACR Approval Process (§ 422.310)

Section 1854 requires that an ACR proposal be submitted each year for each M+C coordinated care plan or M+C private fee-for-service plan, and that premiums be filed for MSA plans. Section 422.310 of this rule sets forth the rules M+C organizations must follow to determine the limits placed on an M+C plan's price structure (premiums, copayments, coinsurance, deductibles, etc.). Since this regulation was not published until after May 1, 1998, new requirements under this rule discussed below will apply to contract periods beginning on or after January 1, 2000. For contract periods beginning before January 1, 2000, M+C organizations shall use the rules promulgated in accordance with section 1876 for risk contractors to determine the limits placed on M+C plan's price structure.

Under the existing ACR process, a M+C organization must establish an initial rate for non-Medicare enrollees for each M+C plan offered. This rate is determined through a community rating method (defined in section 1308 of the Public Health Service Act) or an aggregate premium method. The initial rate is then modified by the relative difference in utilization characteristics of the Medicare population compared to the non-Medicare population included in the initial rate. Additional adjustments may be made with our agreement. Those M+C organizations that do not have a non-Medicare

population cannot establish an initial rate. These M+C organizations will be allowed to use an estimate of the ACR value for a service or services offered using generally accepted accounting principles. These estimated values will be treated as additional adjustments for our review.

The ACR computation places a limit on the beneficiary premiums and cost-sharing amounts of an M+C plan, and we will only approve the beneficiary premiums and cost-sharing amounts proposed by an M+C organization for a specific M+C plan if they do not exceed the ACR limits.

As noted above, § 422.310 contains new requirements for calculating ACRs that will require existing section 1876 contractors to change the methodology they have used to calculate their ACRs under section 1876. We recognize that section 1856(b)(2) provides that consistent with the requirements of Part C, standards established under Part C should be based on standards established under section 1876 to carry our analogous provisions of that section. The requirements in § 422.310 are based on, and fully consistent with, the existing section 1876 requirements in § 417.594. An M+C organization following the methodology set forth in § 422.310 would fully comply with the existing ACR provisions in § 417.594.

However, based upon our years of experience under the section 1876 program, we have determined that the language in § 417.594 permitted HMOs and CMPs to use methods for calculating their ACRs that produced ACRs that we do not believe accurately reflected the statutory standard implemented in that section. Indeed, the existing methodology has been criticized by the General Accounting Office and the Office of the Inspector General as inaccurate, and subject to modification by organizations. The existing methodology also did not provide for necessary adjustments (for example, based upon changes in utilization assumptions in anticipation of changes in cost sharing structures, or changes in Medicare coverage) that we provide for in § 422.310. Also, as discussed below, some of these changes accommodate the fact that some organizations do not maintain data used under the old methodology (service statistics) but do maintain data (cost data) used under the new methodology in § 422.310. Finally, the existing ACR form necessarily has to be changed to adapt to the new options under the M+C program.

For all of the above reasons and others discussed below, pursuant to our authority in section 1856(b)(1) to establish standards for M+C organizations, and consistent with the provision in section 1865(b)(2) that such standards be based on section 1876 standards, we have built on the existing ACR methodology in § 417.594 but refined this methodology in order to ensure the accuracy of ACRs under the M+C program.

Specifically, we have added the following new requirements to the provisions in § 417.594:

1. Revision of data requirements used to develop differences in utilization characteristics of the Medicare population from a relative service ratio to a relative cost ratio (for additional revenue, a relative excess revenue ratio) experienced in a prior period.

2. Separation of the administrative component into two parts—an administrative cost component and a component that reflects revenues collected in excess of costs.

3. Provision for an M+C organization to adjust for relative differences that the organization expects to encounter in the period covered by the ACR that were not reflected in the prior period. Below we discuss each in turn, including where the new process diverges from the former ACR methodology.

Revision of Data Requirements Used to Develop Differences in Utilization Characteristics of the Medicare Population from a Service Ratio to a Cost Ratio Experienced in a Prior Period: Currently, risk contracting plans (HMOs) under section 1876 of the Act use a relative volume/complexity (V/C) factor to modify commercial premiums for each health care component (e.g. inpatient hospital, physician) to account for differences in utilization characteristics between commercial members and Medicare members. The modified commercial premium is the ACR value for that health care component applicable to the Medicare enrollee.

Currently, HMOs are directed to develop the V/C factors using comparative service statistic ratios on a health care component basis. Service ratios require HMOs to supply a large amount of service statistics.

Risk contractors assert that they, as a rule, do not keep service statistics in the same manner, format, and/or detail needed to compute these ratios. Some HMOs have resorted to using statistics gathered from one commercial package to be compared to all Medicare enrollee statistics. Others have used estimations of service statistics (especially for those services not offered by the HMO in the past).

Managed care organizations keep detailed records on the cost of care included in the benefit packages sold. Since the cost of providing medical care is a function of both volume (number of services) and complexity (price of the service), M+C organizations could compare the direct cost of medical care (incurred in a previous period) between the organization's commercial and Medicare populations on an average per enrollee basis to account for differences in utilization characteristics of the respective populations. For those services not offered in the past, the M+C organization could use an estimate of the cost to establish an ACR value for the new service.

We believe this modification of data requirements will make the ACR more accurate, easier to process, and ultimately, easier to verify. Costs could be compared from year to year to establish the reasonableness of the data provided. In addition, cost data as reported could be compared to other required reports and the organization's financial statements. Later, during monitoring visits, costs could be compared to the organization's financial records.

This approach is justified in view of the expanded participation of different types of M+C plans authorized in the BBA. BBA provisions include organizations offering new types of M+C plans that may not have an enrolled commercial population and, without an enrolled commercial population, these organizations would be unable to complete the current ACR. Under the new method, these M+C organizations would be allowed to develop a cost estimate for the purpose of establishing an ACR value for the Medicare population.

Separation of Administrative Component into Two Components—an Administrative Cost Component and a Component that Reflects Revenues Collected in Excess of Costs: Currently, HMOs are directed to bundle that part of the commercial premium that represents any excess revenue over expenses with administration into one component. In § 422.302, we refer to the component of the premium that represents revenue in excess of costs incurred as ''additional revenues.'' Specifically, we define ''additional revenues'' to mean revenues collected or expected to be collected from charges for M+C plans offered by an M+C organization in excess of costs actually incurred or expected to be incurred. Additional revenues would include such things as revenues in excess of expenses of an M+C plan, profits, contribution to surplus, risk margins, contributions to risk reserves, assessments by a related entity that do

not represent a direct medical or related administrative cost, and any other premium component not reflected in direct medical care costs and administrative costs.) The combined component representing administrative and excess revenues was then converted to a Medicare value using the same method the HMO used to compute the amount for commercial enrollees. HMOs have consistently claimed they use a percentage method (For example, administration is calculated as a specific percentage of health care components). In effect, this increases the administration and additional revenues anywhere from 300 percent to 500 percent for Medicare. In addition, this bundling assumes that both administration and additional revenues are similar in nature and should be treated the same.

Under the new ACR, we are requiring M+C organizations to divide the administrative component into two parts and modify each part with a factor that is consistent with each part. We believe this will provide HCFA with data that is both more accurate and more useful.

Administrative costs will be included in the ACR computation in the same manner as they are incurred in commercial premiums. M+C organizations will be required to reveal projected amounts of additional revenues to HCFA for each population group (commercial and Medicare). M+C organizations would be required to justify larger additional revenues projected for the Medicare population in relation to their commercial population.

Construction of a Method for an Organization to Adjust for Relative Differences the Organization Expects to Encounter in the Period Covered by the ACR that Were not Reflected in the Prior Period: Section 1876 allowed for modification of the initial rate by a relative factor of services furnished in a prior period. Implementing regulations did not allow for any other modifications to the initial rate in establishing the ACR for a service or services, and we have since recognized that additional modifications to the initial rate may be necessary. For example, Medicare coverage may be increased from one year to the next. If the organization did not provide the service in the past and no additional modifications to the initial rate were allowed, the organization could not adjust for the new service in its ACR. Organizations also had no method for making adjustments to take into account projected changes in utilization patterns that would result from changes in cost sharing amounts. We have included a provision in this rule to allow for such changes.

M+C organizations will be allowed to further reduce the ACR values so that the ACR values equal the actuarial value of the charge structure of the M+C plan.

6. Requirement for Additional Benefits (§ 422.312)

If the ACR calculation for an M+C plan produces an excess amount (the difference between the average of the M+C per capita rates of payment (APR) and the ACR value (less the actuarial value of original Medicare's deductibles and coinsurance)) for Medicare covered services, the M+C organization is required to use that amount as follows:

- First, the M+C organization may elect to contribute part or all of the excess amount to a stabilization fund;
- Second, the M+C organization may use the remainder to fund additional services not covered by Medicare; and
- Third, the M+C organization must use any remainder to reduce the premium and/or cost sharing allowed for services covered by original Medicare.

A number of rules contained in this section were developed using the rules under section 1876, though certain changes to those rules were made to comply with new provisions in the BBA. For example, the rules for the stabilization fund under section 1876 were largely incorporated in this section. However, section 1854(f)(2) revised the time period and disposition of those funds at the end of that time period. We have incorporated these changes in § 422.312(c).

H. Provider-Sponsored Organizations

This interim final rule makes certain technical and conforming changes to existing subpart H of part 422. These changes are discussed in section II.R. of this preamble.

I. Organization Compliance With State Law and Preemption by Federal Law

1. State Licensure (§ 422.500)

Among the organizational and financial requirements for M+C organizations, section 1855 of the Act requires that an organization shall be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers an M+C plan. (An exception to the licensure requirement is made for PSOs, as provided for in part 422 subpart H.) Section 1855(b) specifies the level of risk that an organization assumes under an M+C contract (i.e., full risk for the M+C benefit package), and the extent to which the organization may insure against such risk or may pass off all or part of the risk to subcontracting providers. The requirements of the statute result in a two-pronged test of appropriate licensure, consisting of the licensure requirement itself and a scope of licensure requirement.

Licensure and Scope of Licensure: With regard to the licensure requirement, although the BBA uses the term ''licensure,'' we have interpreted the provision as requiring a license or some other type of certification (such as a certificate of authority) that represents permission granted by the appropriate State authority for the organization to operate within the State as a risk-bearing entity offering health insurance or health benefits. Having met the State licensure requirement, an organization must also show that the ability to offer an M+C plan of the type they wish to offer is within the scope of its State licensure or State authorization. For example, an organization that offers only a prepaid dental plan in a State could be licensed as a risk-bearing entity, but its licensure status may not permit the organization to offer a health benefits plan that includes a comprehensive range of services, as would be necessary under an M+C contract. Similarly, a State may require an organization that is a licensed HMO to obtain separate licensure as an indemnity insurer in order to offer an M+C point-of-service (POS) plan, on the basis that the HMO scope of licensure does not include the ability to offer what is considered an indemnity product. (A State's requirement that an organization have an indemnity license in order to offer a POS product is not superseded by the Federal preemption provisions discussed below.)

In some States, a Medicaid HMO may operate without a license from the department of insurance or other State agency that licenses organizations offering health benefits or health insurance in the commercial and Medicare markets. The Medicaid plans operate under the authority of the State Medicaid agency, which may be the agency establishing solvency standards for such organizations, as required by section 1903(m)(1)(A)(ii). The State authorization for these plans may be viewed as a limited scope licensure, enabling plans to operate as Medicaid contractors only, and not in other segments of the health insurance market.

To establish the licensure status of organizations, and in particular to determine compliance with scope of licensure requirements, we will require, as part of the application process for

new applicants, documentation that both the licensure and scope of licensure requirements are met. Organizations must provide verification from the appropriate State regulatory body authorized to license Medicare risk products demonstrating that the licensure status of the organization enables it to offer the M+C plan, or plans, it intends to offer. This would ensure that, in the case of an organization only authorized to offer a Medicaid plan, for example, solvency standards appropriate to an M+C product are met. In the case of non-commercially licensed entities, we are requiring that they obtain a special certification from the State that they meet appropriate solvency standards.

As noted in the BBA, ''The fact that an organization is licensed in accordance with paragraph [1855(a)](1) does not deem the organization to meet other requirements imposed under this part'' (1855(a)(3)). That is, while the State licensure requirement is imposed on all plans as a prerequisite for contracting as an M+C organization, licensure in and of itself does not guarantee that an organization will be able to obtain an M+C contract. The organization must meet other applicable requirements of this part in order for us to grant an M+C contract.

2. Federal Preemption of State Law (§ 422.502)

Section 1856(b)(3)(A) of the Act provides for a Federal preemption of State laws, regulations, and standards affecting any M+C standard if the State provisions are inconsistent with Federal standards (a preemption policy we refer to below as a general preemption). There is also a specific preemption of State laws (1856(b)(3)(B)) in three areas where Federal standards ''preempt the field''; that is, regardless of whether State laws are inconsistent or not, Federal standards preempt State law, regulations, and standards. The general and specific preemption of State law applies to ''Medicare benefits and Medicare beneficiaries,'' as stated in the conference report that accompanied the BBA. The BBA preemption provisions do not extend to non-Medicare enrollees or activities or non-Medicare ''lines of business'' of organizations that have M+C contracts.

Prior to the BBA, section 1876 of the Act (governing Medicare risk and cost contracts with HMOs and competitive medical plans) did not contain any specific preemption provisions. However, section 1876 requirements could preempt a State law or standard based on general constitutional Federal preemption principles, consistent with the provisions of Executive Order 12612 on Federalism. Under the guidelines of the Executive Order, section 1876 requirements did not preempt a State law or standard unless the law or standard was in direct conflict with the Federal law, or it prevented the organization from complying with the Federal law. Put another way, if Federal law permitted the HMO to do what State law required, there was no preemption. In practice, rarely, if ever, did Federal law preempt State laws affecting Medicare prepaid plans. For example, Medicare risk plans operating in States with mandated benefit laws were generally required to comply with such State laws. Compliance with the State mandated benefit law was not viewed as interfering with the ability of plans to function as Medicare risk contractors under Federal standards. (Because the BBA preemption applies only to M+C plans, this approach to preemption issues will continue to apply to cost contracts governed by section 1876 rules.)

General Preemption: The general preemption provision of the BBA will be applied in the same way that the Executive Order has been applied, in that State laws or standards will be preempted only when they are inconsistent with M+C standards, as clearly indicated in the statute. Because the BBA requires that PSOs operating under a waiver of the State licensure requirement must comply with State quality and consumer protection standards, it seems clear that the Congress expected States, in some cases, to have more rigorous or more comprehensive standards for quality and consumer protection which would enhance, rather than duplicate or be subsumed under, the M+C standards for quality and consumer protection. Thus, unless one of the specific preemptions discussed below applies, State laws or standards that are more strict than the M+C standards would not be preempted unless they prevented compliance with the M+C requirements. This is consistent with the BBA conference report language that notes that State laws apply if they provide ''consumer protections in addition to, or more stringent than'' the BBA. The BBA also provides that the quality and consumer protection standards with which PSOs must comply include only those requirements ''generally applicable to M+C organizations and plans in the State'' which are ''consistent with the standards'' of the BBA. That is, there are likely to be quality and consumer protection standards imposed by States that all M+C plans must comply with, and for which there is no Federal preemption.

Specific Preemption: Though the general preemption provision will be applied in the same way that the Executive Order has been applied, for the three areas in which the Congress provided for a specific preemption of State laws, the M+C standards supersede any State laws and standards. These three areas are:

- Benefit requirements:
- Requirements relating to inclusion or treatment of providers; and
- Coverage determinations (''including related appeals and grievance processes'').

We are adopting a narrow interpretation of the applicability of the three areas of specific preemption, which we believe is justified by the conference report language and the overall structure of the BBA in its delineation of the relative roles of the State and Federal governments. Under the BBA, States have exclusive authority (other than in the case of PSOs) to make the determination of whether organizations are eligible to enter into M+C contracts, while under section 1876 of the Act, it was the Federal Government that designated ''eligible organizations'' (HMOs under title XIII of the Public Health Service Act (a Federal designation) or competitive medical plans (also a Federal designation)). Under section 1876, the Federal Government also determined solvency standards for organizations, while under the BBA this becomes a State responsibility (other than for PSOs). The conference report (p. 638) also clarifies the intended scope of preemption in the three specific areas. The report indicates the conferees seek to put M+C on a par with ''original fee-for-service,'' where the ''Federal government alone set legislative requirements regarding reimbursement, covered providers, covered benefits and services, and mechanisms for resolving coverage disputes.'' The conferees wish to ''[extend] the same treatment to private M+C plans providing Medicare benefits to Medicare beneficiaries.''

Using the analogy of original Medicare, Federal law preempts State laws and standards in certain specific areas. Under original Medicare: States cannot specify what must be included as a Medicare benefit; States do not specify the conditions of participation of Medicare providers (though they license providers and practitioners and determine their scope of practice); States may not specify how a coverage determination is to be made with respect to whether or not the Medicare program covers a benefit; and a State

does not determine the type of appeal mechanism that is to be used to appeal a coverage decision made by a Medicare carrier or intermediary with respect to a Medicare benefit. For M+C plans, the specific preemption of State laws in the three areas would prevent, for example, the application of mandated benefits laws; ''any willing provider'' laws and other laws mandating the inclusion of specific types of providers or practitioners; or laws that supplant or duplicate the Medicare coverage determination and appeal process as it relates to coverage of benefits under the M+C contract. However, States may have various laws and requirements that could still apply to

- Benefits (for example, a plan could be required to have a toll free number to answer benefit questions),
- Providers and practitioners generally in the State (e.g., they must all be licensed by the State and comply with scope of practice laws), and
- Laws and standards which could apply to disputes between members and health plans, as discussed below.

Under our narrow construction of the specific preemptions, and consistent with our definition of the term ''benefits'' at § 422.2, the specific preemption of benefit laws does not extend to State laws and standards relating to cost sharing or other financial liability standards for enrollees of health plans, though we are inviting comments on our position, outlined below, that cost sharing should not fall under the benefits preemption, as well as comments on whether there are types of cost sharing that should or should not be included in the benefits preemption.

Thus, a State law prescribing limits on cost sharing generally, or limits on cost sharing that can be imposed for specific benefits, would not be preempted. If the benefit to which the State cost sharing limits apply is not a Medicare covered benefit, however, the limits on cost sharing would only apply if the M+C organization *chooses* to offer the benefit in question. Thus, to the extent that limits on cost sharing are linked to a benefit mandate, the cost sharing limits could be seen to be *indirectly* ''preempted'' in that the obligation to provide the benefit to which they apply is preempted. If the M+C organization chooses not to provide the benefit that would otherwise be mandated under a preempted benefit mandate, the cost sharing limits that apply to that benefit would never come into play. We note that while cost sharing limits are not specifically preempted under the benefits preemption in section 1856(b)(3)(B)(i) and § 422.402(b)(1), cost sharing limits are still subject to the general preemption in section 1856(b)(3)(A) and § 422.402(a). Thus, to the extent the cost sharing limit would be inconsistent with M+C provisions, it would be preempted. An example of State cost-sharing requirements being preempted because they are inconsistent with M+C provisions would be a State requirement that requires all insurers and health plans to pay 100 percent of the cost of a particular service (e.g., mammography screening or other preventive care). In the case of an M+C MSA plan, we would argue that the general preemption provision applies, because the State requirement is inconsistent with the basis structure of a high-deductible plan under which covered services are not payable under the plan until the deductible is met.

To address a specific question that has arisen, State laws requiring direct access to particular providers (either contracted by the M+C organization or not under contract), and State laws requiring, for example, a second opinion from non-contracted physicians, would be superseded by the benefit and provider participation preemptions (though M+C standards in these regulations dealing with access to particular providers may have an effect that is similar to that of State laws that are superseded). This is because these requirements in essence mandate the ''benefit'' of access to a particular provider's services even where the services of that provider would not otherwise be a covered benefit.

We are also adopting a narrow interpretation of the scope of preemption of coverage determinations. Coverage determinations are made initially by M+C organizations and may be appealed as provided for under subpart M of these regulations. Our view is that the types of decisions related to coverage included in this specific preemption are only those determinations that can be subject to the appeal process of subpart M. These are decisions about whether an item or service is covered under the M+C contract and the extent of financial liability beneficiaries have for the cost of covered services under their M+C plan. The Medicare appeal process applies to basic benefits, mandatory supplemental benefits, and optional supplemental benefits offered under an M+C contract. The specific preemption makes the Medicare appeal process the exclusive remedy for disputes over coverage determinations, displacing any State grievance or appeal process that might otherwise be available in such cases. However, the specific preemption does not preempt State remedies for issues other than coverage under the Medicare contract (i.e. tort claims or contract claims under State law are not preempted). The same claim or circumstance that gave rise to a Medicare appeal may have elements that are subject to State remedies that are not superseded. For example, an M+C organization's denial of care that a beneficiary believes to be covered care is subject to the Medicare appeals process, but under our interpretation of the scope of the specific preemption on coverage decisions, the matter may also be the subject of a tort case under State law if medical malpractice is alleged, or of a state contract law claim if an enrollee alleges that the M+C organization has obligated itself to provide a particular service under State law without regard to whether it is covered under its M+C contract.

We are seeking public comments on our interpretation of the applicability of the three areas of pre-emption specifically the exclusion of cost sharing and financial liability standards from the federal pre-emption and the exclusion of direct access to particular providers.

As noted above, where the BBA preempts State laws and standards, any Federal preemption based on the BBA applies only to the Medicare ''line(s) of business'' of an M+C organization (i.e., Medicare enrollees). As such, there would be no Federal preemption of State laws which are applicable to other enrollees of the organization. Additionally, there would be no Federal preemption of State laws which are applicable to arrangements outside the scope of the BBA, such as arrangements between employers and M+C plans for the provision of negotiated employer group benefits discussed at § 422.106 of these regulations. Neither the specific nor the general preemption would apply to any aspect of such arrangements.

3. Prohibition on State Premium Taxes (§ 422.404)

Section 1854(g) of the Act, introduced in the BBA, provides that ''No State may impose a premium tax or similar tax with respect to payments to M+C organizations under section 1853.'' Section 4002(b)(4) of the BBA makes the prohibition on premium taxes applicable to risk-sharing contracts operating under section 1876 effective the date of enactment of the BBA. This prohibition does not apply to enrollee premium payments made to M+C plans, which are authorized under section 1854.

The regulations provide clarification on the applicability of the prohibition of State premium taxes. The BBA does not

define the term ''State,'' but elsewhere in the Medicare statute (1861(x), referring to 210(h) of the Act), the term ''State'' is defined to include the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa. The regulations include this definition of State for purposes of the scope of the premium tax prohibition.

The BBA is also silent as to whether the prohibition of premium taxes includes county taxes or taxes by other governmental entities within a State. The Federal Employees Health Benefits Program (FEHBP) statute, on the other hand, has more specific language on the applicability of the exemption from premium taxes. The FEHBP statute specifically extends the prohibition to ''any political subdivision or other governmental authority'' of a State (5 U.S.C. 8909(f)(1)).

The BBA conference report does not provide any clarification on this issue. However, a July 31, 1997 summary of the provisions of the BBA prepared by the Senate Finance Committee (''Summary: Health and Welfare Provisions in the Balanced Budget Act of 1997''), stated that ''[t]he current law on federal preemption of state premium taxes or fees on Federal payments from the FEHBP to health plans will be extended to Federal payments to M+C plans and other health plans receiving capitated payments from the Medicare Trust Funds.'' Although the language of the BBA prohibition is not as specific as the FEHBP language, we are clarifying in these regulations that the prohibition does apply to any political subdivision or other governmental authority within a State. We believe such an interpretation is necessary because counties and other State authorities derive their powers from the State. Thus, any prohibition of State actions contained in a Federal statute should be interpreted as prohibitions on actions at any level of State government or any State or local governmental body within a State.

The BBA does not define the phrase ''premium tax or other similar tax,'' other than by reference to the applicability of such a tax to revenue received from the Federal Government for health plan enrollees. Relying again on the FEHBP statute, we have included a provision in the regulations (§ 422.404(b) that serves to clarify the scope of what constitutes a prohibited premium tax. The FEHBP statute expressly permits States to impose taxes on the profits arising from participation as an FEHBP plan, to the extent that the tax on profits, or other taxes or fees, are general business taxes. We have included a similar exception because such taxes are not taxes applied directly and exclusively to premium revenues, and therefore should not be prohibited under section 1854(g).

The BBA premium tax prohibition does not provide for any exception to the prohibition based on the purpose of the tax. For example, some States are using a broadly applicable premium tax to fund health care coverage for individual State residents who might otherwise be uninsured (e.g., financing a State high-risk pool), or to fund a State guaranty fund that could potentially benefit enrollees of an M+C plan in the event of insolvency. Although such premium taxes do provide a social good, and may yield a direct benefit to M+C organizations and their enrollees, there are no exceptions to the premium tax prohibition included in the BBA or in these regulations. By not having allowed any exceptions, we would note that, to the extent participation in a State guaranty fund is used as means of satisfying State (or Federal) requirements for protections in the event of insolvency, M+C organizations that would otherwise have participated in the guaranty fund by paying the premium tax are likely to be required to meet alternative insolvency requirements. An M+C organization may also choose to voluntarily pay premium taxes in order to participate in such a fund.

J. Subpart J of Part 422

Subpart J of part 422 is being reserved.

K. Contracts with M+C Organizations

1. Definitions (§ 422.500)

Section 422.500 of subpart K contains definitions germane to subpart K that address provisions pertaining to contracts with M+C organizations. These definitions, for the most part, have been imported from part 417 under our authority from section 1856(b)(2). The lone exception, *Party of Interest* has been clarified in paragraph (3) to include non-profit entities.

2. General Provisions (§ 422.501)

Section 1857(a) provides that the Secretary will not permit an organization to operate as an M+C organization unless it has entered into a contract with HCFA. The statute also provides that the contract may cover more than one M+C plan.

An applicant, however, must meet certain requirements before HCFA can consider entering into a contract with it. First, in accordance with section 1855(a)(1), the applicant must be licensed (or if the state does not license such entities, hold a certificate of authority/operation) as a risk-bearing entity in the State in which it wishes to operate as an M+C organization; section 1855(a)(2), however, allows for a waiver of this requirement for Federally-waivered PSOs under certain circumstances. Second, the applicant must meet the minimum enrollment requirements specified at section 1857(b). These requirements provide that the organization must have at least 5,000 (or 1,500 if it is a Federally-waivered PSO) individuals receiving health benefits from the organization or at least 1,500 (or 500 if it is a PSO) individuals receiving benefits in a rural area. Section 1857(b)(3) gives the Secretary the authority to waive the minimum enrollment requirements for the first 3 contract years.

Third, an M+C organization must demonstrate certain administrative and managerial capabilities that we believe are essential for HCFA to examine prior to agreeing to contract with any applicant as an M+C organization. For this reason, pursuant to section 1856(b)(2) which provides for the adoption of regulations implementing section 1876, we have adopted the administration and management requirements from §§ 417.120 and 417.124 and have applied them to M+C organizations. In addition, pursuant to our authority in section 1856(b)(1) to establish standards under Part C by regulation, we will require that all M+C organizations establish a plan for complying with all applicable Federal and State standards. The compliance plan must include written policies, procedures, and standards of conduct, the designation of a compliance officer accountable to senior management of the organization, provisions for internal monitoring, auditing, accountability, and an adhered to process for reporting violations of law by the organization or their subcontractors.

Further, pursuant to our authority in section 1856(b)(1) to establish standards for M+C organizations by regulation, we are in this rule establishing an additional condition for entering into an M+C contract. Under this rule, an entity that is accepting new enrollees under a section 1876 cost contract will be ineligible to enter into an M+C contract covering the area it serves under its cost contract. Our reason for establishing this rule is to eliminate the potential for an organization to encourage higher cost enrollees to enroll under its cost contract while healthy enrollees are enrolled in its risk-based M+C plan. This rule is consistent with our longstanding policy that entities not

have both a risk and cost contract under section 1876 in the same area.

Further, we provide at § 422.501(b) that in order to be eligible to contract as an M+C organization, an applicant organization that held a prior contract terminated by HCFA under § 422.510 within the past five years.

Section 1857(c)(5) authorizes the Secretary to enter into contracts with organizations without regard to provisions of law or regulations that the Secretary determines to be inconsistent with the furtherance of the purpose of Title XVIII of the Act. Based on this authority, we provide in § 422.501(c) that HCFA may enter into contracts under part 422 without regard to the Federal and Departmental acquisition regulations set forth in title 48 of the CFR.

Further, section 1857(d)(1) and (2) provide for the auditing of the financial records of at least one third of M+C organizations annually, and the inclusion of specified inspection and auditing rights in M+C contracts. We have incorporated these requirements in § 422.501(d). We likewise specify related requirements that enable HCFA to do so.

Since section 1857(a) allows that an M+C contract may cover more than one M+C plan, we have added paragraph (e), ''Severability of contracts,'' through our authority in section 1856(b)(1). The contract provides that upon HCFA's request (1) the contract will be amended to exclude any M+C plan or State-licensed entity specified by HCFA, and (2) a separate contract for any such excluded plan or entity would be deemed to be in place when such a request is made.

National Contracting

The BBA does not specifically define or otherwise address the issue of national contracting. While we are interested in national contracting, we have not specified it in the regulations and welcome comment on this concept. One option we are considering would allow an M+C applicant to request that HCFA enter into a national contract with the applicant if the applicant holds license as a risk-bearing entity in each state where it operates or has a waiver as provided in § 422.370. The applicant M+C organization would have the option of having a uniform premium and benefit plan across the country, with one service area and a national ACR proposal.

We are considering a different concept of a national agreement with national chain organizations. This concept would apply to those chain organizations that enter into separate contracts in multiple States. The agreement would allow for the chain organization to establish a uniform policy across all of its states as to marketing, quality assurance, utilization review, claims processing, etc. HCFA would have to approve the national policy procedures. HCFA would continue to contract separately with individual, albeit related, M+C organizations affiliated through common ownership or control. We would continue to monitor operational activities for each organization in each State, but having approved national policy, our review at the State and local level would be reduced.

3. Contract Provisions (§ 422.502)

Section 422.502 of this rule sets forth the provisions and related requirements for contracts between HCFA and M+C organizations. In general, Medicare beneficiaries may not elect to enroll in an M+C plan offered by an M+C organization, and no payment will be made to the M+C organization, unless the Secretary enters into a contract with the organization. The provisions that describe this relationship between the Secretary and the M+C organization are based on Part C of title XVIII of the Act and on Medicare contract requirements derived from subparts C and L of part 417.

The provisions of the Act as added by the BBA are generally silent with regard to the specific provisions that must be included in the contract between the M+C organization and HCFA. The Act does, however, specify at section 1857(a) that the contract must provide that the organization agrees to comply with the applicable requirements, standards, and terms and conditions of payment of Part C of title XVIII of the Act. In addition, section 1857(e) provides that the contract shall contain such other terms and conditions not inconsistent with Part C of title XVIII of the Act that the Secretary may find necessary and appropriate. Included in § 422.502(a), ''Agreement to comply with regulations and instructions,'' are the following contract conditions:

- The M+C organization must agree to accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments. The M+C organization agrees that it will comply with the prohibition in § 422.108 on discrimination in beneficiary enrollment.
- The M+C organization must agree to provide the basic benefits as required under § 422.101 and to the extent applicable, supplemental benefits under § 422.102.
- The M+C organization must agree to provide access to benefits as required under subpart C of part 422. All benefits covered by Medicare must be provided in a manner consistent with professionally recognized standards of health care.
- The M+C organization agrees to disclose information to beneficiaries as required under § 422.110.
- The M+C organization must agree to operate a quality assurance and performance improvement program, and to have an agreement for external quality review as required under subpart D of part 422.
- The M+C organization must agree to comply with all applicable provider requirements in subpart E of part 422, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, and limits on physician incentive plans.
- The M+C organization will agree to comply with all requirements in subpart M governing coverage determinations, grievances, and appeals.
- The M+C organization will comply with the reporting requirements in § 422.516 and the requirements for submitting encounter data to HCFA in § 422.257.
- The M+C organization agrees that it will be paid under the contract in accordance with the payment rules under subpart F of part 422.
- The M+C organization will develop annual adjusted community rate proposals and submit all required information on premiums, benefits, cost sharing by May 1, as provided in subpart G of part 422.
- The M+C organization agree that its contract may be terminated or not renewed in accordance with subparts K and N of part 422.
- The M+C organization will agree to comply with all requirements that are specific to a particular type of M+C plan, such as the special rules for private fee-for-service plans in §§ 422.114 and 422.216 and the M+C MSA requirements in §§ 422.56, 422.103, and 422.262.
- The M+C organization will agree to comply with the confidentiality and enrollee accuracy requirement in § 422.118.
- The M+C organization agrees that complying with the aforementioned contract conditions is material to performance of the contract.

Contract requirements that were either not required of HMOs and CMPs

under section 1876, or have been modified to implement the M+C program follow:

- The M+C organization must possess the capabilities to communicate with HCFA electronically.
- The M+C organization is required to provide prompt payment of covered services if these services are not furnished by a provider under contract or agreement in an M+C plan's health services delivery network. Under section 1876, the prompt payment requirement was limited to noncontracting providers. Section 1857(f) duplicates this requirement and adds to it the requirement that if the Secretary determines that an M+C organization fails to pay claims promptly, the Secretary may provide for direct payment of the amounts owed providers. When this occurs, the Secretary reduces the amount of the M+C organization's monthly payment to account for payments to these providers. We explain the full implications of this requirement in the discussion below pertaining to § 422.520.
- Pursuant to our authority in section 1856(b)(1) to establish standards under Part C, we are requiring that M+C organizations maintain records for 6 years. The standard for retention of records for HMO and CMPs was 3 years. We are changing the retention period from 3 years to 6 years so as not to prematurely foreclose our ability to address fraudulent or other abusive activities.
- Pursuant to our authority at section 1856(b)(1) to establish standards under Part C, we specify requirements relating to M+C organizations providing access to facilities and records at § 422.502(e). In this section we assert that M+C organizations allow HHS, the Comptroller General, or their designees to evaluate, through inspection or other means, all aspects of medical services furnished to Medicare beneficiary enrollees, the facilities of M+C organizations, and enrollment and disenrollment records of M+C organizations. We further provide that HHS, the Comptroller General, or their designees may audit, evaluate, or inspect all facilities and records as the Secretary may deem necessary to enforce an M+C contract. HHS's, the Comptroller General's, and designee's right to inspect such facilities and records extends through 6 years from the date of the contract period or completion of any inspection or audit activity, whichever is later. Exceptions to this 6-year inspection timeframe can occur in instances when: (1) HCFA determines there is a special need to retain particular records or a group of records for a longer period and notifies the M+C organization at least 30 days before the normal disposition date, (2) there has been a termination, dispute, or fraud or similar fault by the M+C organization, in which case the retention may be extended to 6 years from the date of any resulting final solution of the termination, dispute, or fraud or similar fault, or (3) HCFA determines that there is a reasonable possibility of fraud, in which case it may inspect, evaluate, and audit the M+C organization at any time.
- Pursuant to our authority in section 1856(b)(1) to establish standards under Part C, and the provision in section 1856(b)(2) for adopting section 1876 standards, we have included certain disclosure requirements from § 417.486 in § 422.502(f). We have also included additional disclosure requirements to reflect new reporting requirements in § 422.516.
- At § 422.502(f)(2), we add the requirement that M+C plans submit to HCFA specific information necessary to evaluate and administer the program and to enable beneficiaries to exercise informed choice in obtaining Medicare services. Section 1851(d) authorizes the Secretary to obtain this information to enable HCFA to fulfill its responsibility to develop activities to disseminate broadly information to current and prospective Medicare beneficiaries in order to promote an active, informed selection among such options.
- Pursuant to section 1851(b)(4)(B), we have specified requirements at § 422.502(b)(2)(vii) that M+C organizations offering MSA plans disclose to HCFA information that will enable HCFA to evaluate the impact of permitting enrollment in MSA plans.
- Enrollee financial protection provisions are addressed at § 422.502(g). The first item protects beneficiary enrollees from incurring liability for payment of any fee that M+C organizations are legally obligated to bear. Section 422.502(g) contains the enrollee financial protection that has applied to HMO and CMP enrollees under § 417.122 (a)(1), which was made applicable to all section 1876 contractors under § 417.407(f). The beneficiary protection at 422.502(g)(1) is designed to protect beneficiary enrollees from being held financially responsible for fees for which the M+C organization is legally liable. Under the provision, we assert that M+C organizations protect beneficiary enrollees in two ways. First, through inclusion, hold harmless language in its written agreements with the providers that comprised the M+C plan's Medicare provider network. And pursuant to our rulemaking authority at section 1856(b)(1), we also specify that M+C organizations must indemnify beneficiary enrollees for the organization's legal obligations that are derived from health care services provided to enrollee beneficiaries by providers that have not entered into a written agreement to participate in the M+C organization's Medicare provider network. The beneficiary protection at 422.502(g)(2) afford beneficiaries protection against loss of benefits for which the M+C organization is legally obligated to pay. Except in the case of PSOs that have been awarded Federal waivers (see subpart H), States have the primary responsibility under Part C for determining whether an M+C organization has sufficient reserves to assume the risk it takes on under an M+C contract. The State that licenses the entity under applicable State law determines whether an entity has sufficient financial reserves to enter into an M+C contract.

Congress has given HCFA some ongoing responsibility concerning solvency, however. In section 1857(d)(4)(A)(i), M+C organizations are required to provide the Secretary with such information ''as the Secretary may require demonstrating that the organization has a fiscally sound operation.'' Accordingly, we believe that it is appropriate, under our authority in section 1856(b)(1) to establish standards under Part C to require (in § 422.502(g)) that an entity that already has an M+C contract demonstrate to HCFA that it has protections in place ensuring that beneficiaries will not be held liable for the entity's debts. We believe that this can be seen as part of having a fiscally sound operation as provided for in section 1857(d)(4)(A)(i).

- The subsection entitled ''Requirements of Other Laws and Regulations'' at § 422.502(h) requires that contracts reflect the M+C organization's obligations under other laws, specifically, the Civil Rights Act of 1964, the Age Discrimination Act of 1975, the Americans with Disabilities Act, other laws applicable to recipients of Federal funds, and all other applicable laws and rules.
- Pursuant to our authority under section 1856(b)(1) to establish standards under Part C, paragraph (i) of § 422.502 contains requirements that apply to related entities, contractors, and subcontractors of an M+C organization. These requirements promote an M+C organization's accountability and program integrity.

The requirements in paragraph (i) recognize that organizations that are likely to apply for M+C contracts commonly enter into business